

## 8. Compliance

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## 8.1 About the Corporate Compliance Program

A Corporate Compliance Program

- Ensures that facilities adhere to all pertinent Federal and State health care program laws, regulations, and guidelines.
- Serves as a mechanism for preventing and reporting any breach of those laws and regulations that fall within specified criteria.

A freestanding compliance program helps to ensure independent and objective legal reviews and financial analysis of an organization's compliance efforts and activities.

Based on guidelines of the Office of Inspector General (OIG) and requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), an effective compliance program includes the following elements:

- Implementing written policies, procedures, and standards of conduct
- Designating a Compliance Officer and a Compliance Committee
- Conducting effective training and education
- Developing effective line of communication
- Enforcing standards through well-publicized disciplinary guidelines
- Conducting internal monitoring and auditing activities
- Responding promptly to detected offenses and developing corrective actions

## 8.2 Implementing Written Policies and Procedures

Written policies and procedures are a central element of any compliance program. They help to reduce the possibility of erroneous claims and fraudulent activity by

- identifying risk areas for the provider
- establishing tighter internal controls to counter those risks, while helping to identify any aberrant billing practices

IHS facilities should establish an integrated set of policies and procedures and general sanctions for violations of compliance regulations.

### 8.3 Designating a Compliance Officer and Committee

Each Area will designate a **Corporate Compliance Officer**, who will have the authority and responsibility to administer and manage all tasks related to establishing, monitoring, and updating the Corporate Compliance Program. To ensure success of the program, each Area Corporate Compliance Officer (ACCO) will

- Have direct access to the Area Director, helping to ensure that a system of checks and balances is established to effectively achieve the goals of the compliance program.
- Provide coordination with each Service Unity, communicating with parallel positions in each facility.

Additionally, each Service Unit will designate a Compliance Officer, who will be responsible for overseeing the administration of the compliance program for their Service Unit. The Service Unit Compliance Officer, in coordination with the ACCO, will be responsible for directing all compliance activities within the Service Unit.

The **Corporate Compliance Committee** will be responsible for

- Guiding and supervising the implementation of the Corporate Compliance Program plan.
- Assisting with the implementation of compliance policies and procedures, in accordance with the directives outlined in the Corporate Compliance Plan.

### 8.4 Conducting Effective Training and Education

Significant elements of the Corporate Compliance Program include proper education and training of all IHS facility personnel, including directors, managers, employees, physicians, and other health care professionals; as well as continual retraining of personnel at all levels.

Education activities include attending seminars and courses related to

- Federal and State statutes, regulations, and guidelines
- private payer policies
- coding and billing requirements
- claim development and submission processes

Training will be targeted to personnel whose actions affect the accuracy of claims submitted to the government, such as coding, billing, and cost reporting, and the duty to report misconduct.

## **8.5 Developing Effective Lines of Communication**

There should be open communication between the Corporate Compliance Officer and the Compliance Officers and all employees at the facilities, so that the potential for fraud and abuse is substantially reduced. Examples of ways to maintain lines of communication include:

- Hotlines
- E-mails
- Memos
- Newsletters

Hotline numbers for accepting anonymous reporting should be posted in conspicuous locations at all facilities.

Confidentiality and retaliation policies and procedures must be in place and be distributed to all employees. For example, a whistle-blower policy should be in place to encourage the reporting of incidents of potential fraud in a safe environment without fear of retaliation.

All reported incidents should be documented and investigated promptly to determine veracity.

### **8.5.1 Developing an Effective Communication System**

A compliance program's system for effective communication should include the following:

- The requirements that staff report conduct that a reasonable person would, in good faith believe to be fraudulent or erroneous
- Creation of a user-friendly process, such as an anonymous drop box, for effectively reporting fraudulent or erroneous conduct
- Provisions in the policies and procedures which state that a failure to report fraudulent or erroneous conduct is a violation of the compliance program
- Development of a simple and readily accessible procedure to process reports of fraudulent or erroneous conduct

- Utilization of a process that maintains the confidentiality of the persons involved in the alleged fraudulent or erroneous conduct and the person making the allegation
- Provisions in the policies and procedures that there will be no retribution for reporting conduct that a reasonable person acting in good faith would have believed to be fraudulent or erroneous

## **8.6 Enforcing Standards through Well-Publicized Disciplinary Guidelines**

Comprehensive policies and procedures must be in place, which define the degrees of disciplinary actions that can be imposed on directors, managers, employees, physicians, and other health care professionals for failing to comply with an Area/facility's standards and policies and procedures, and applicable Federal and State laws and regulations.

Directors, managers, supervisors, medical staff, and other health care professionals should be held accountable for failing to comply with, or for the foreseeable failure of their subordinates to adhere to, the applicable standards, policies and procedures, and laws. Additionally, failure to detect and report violations of the compliance program may be subject to discipline, and will be noted in the disciplinary procedure.

The consequences of non-compliance should be applied and enforced consistently. Disciplinary actions could range from oral warnings to suspension, privilege revocation, or termination, based on the seriousness and type of violation.

Managers and supervisors will be educated regarding their responsibility to discipline employees in an appropriate and consistent manner. Depending on the violation, some issues will be handled at the department level, while more serious violations may need to be resolved by a more senior manager or director. Checks will also be performed to insure that no employee is included on the OIG or GSA list of individuals excluded from participation in a Federal health care or Government procurement program.

All staff will receive a copy of the disciplinary policy for compliance violations and will be asked to sign a statement of receipt of the policy. A statement that all disciplinary action will be taken on a fair and equitable basis should also be included.

Any communication that results in the finding of non-compliant conduct will be documented in the compliance files, including the date of the incident, name of the reporting party, name of the person responsible for taking action, and the follow-up action.

### **8.6.1 Employment Guidelines**

Area offices and facility policies must prohibit the employment of individuals or execution of contracts with companies, who have been recently convicted of a criminal offense related to health care, or who are listed as debarred, excluded or otherwise ineligible for participation in Federal health care programs, as defined by 42 W.S.C. 1320a-7b(f).

Employment applications shall require the applicant to disclose any criminal conviction as defined by 42 U.S.C. 1320a-7(i), or any exclusion action.

Any individual or contractor who has criminal charges or is pending debarment or exclusion shall be removed from any direct responsibility for or involvement in any Federal health care program. Should the individual or contractor be found guilty of such charges, or be debarred or excluded, will be terminated.

New employees, who will have discretionary authority to make decisions that may involve compliance with the law or compliance oversight, shall be subject to a reasonable and prudent background investigation, which includes a reference check.

Any potential employee or contractor, who has been officially reinstated into the Medicare and Medicaid programs by the OIG, may be considered for employment upon such proof of reinstatement.

## **8.7 Conducting Internal Monitoring and Auditing Activities**

Ongoing auditing and monitoring activities are critical to a successful compliance program and should be key features in any annual review of the effectiveness of the compliance program.

The Area Corporate Compliance Officer (ACCO) will

- Recommend and facilitate auditing and monitoring of identified risk areas related to compliance with laws and regulations, and organizational policies, procedures, and standards of conduct.

- Provide guidance and assistance to those conducting and/or supervising compliance reviews.
- Verify completion of compliance reviews and validate corrective measures that address any weaknesses identified by the process
- Report the general status and outcome of compliance auditing and monitoring to the Governing Board.

For further discussion on monitoring and auditing activities, see Part 1, Chapter 8, Section 8.9, “Evaluating and Monitoring Compliance-Related Risks.”

## **8.8 Responding to Detected Offenses and Developing Corrective Actions**

According to the OIG, one of the seven essential elements for an effective compliance program is the investigation and remediation of identified systemic problems.

Audit and review follow-up are integral parts of good management and an effective compliance program. To ensure that identified problems and/or weaknesses do not recur, it is essential that management take corrective action on findings and recommendations.

## **8.9 Evaluating and Monitoring Compliance-Related Risks**

The Area Director (AD) and Service Unit Directors (SUD) are tasked with two general types of monitoring and auditing requirements:

- The AD and SUD should be responsible for ensuring that the elements of the compliance program remain effective.
- The AD and SUD should ensure that areas of risk are monitored consistently and appropriately. However, individual Department managers and/or Area Program managers should take the lead in addressing their particular areas of risk, as they have a better understanding of those risk areas.

Although it is not necessarily the responsibility of the AD and SUD to conduct audits, they should coordinate efforts to secure the resources and experts (internal or external auditors) needed to perform compliance audits.

### **8.9.1 Benchmarking**

The OIG recommends that before implementing a compliance program that an organization benchmark their compliance performance and knowledge. These assessments can be performed by outside consultants or internal staff with authoritative knowledge of compliance requirements. The benchmarks would become a baseline to ensure that the elements of the compliance program are operating effectively.

To complete their initial reviews, officials should consider

- visiting sites where procedures associated with compliance are performed
- Interviewing personnel involved in management, operations, coding, claim development, and submission, patient care, and other activities associated with compliance risk areas.
- using surveys to collect information associated with compliance risk areas

### **8.9.2 Performing Periodic Reviews**

Besides the benchmark review, periodic reviews (at least annual) should be performed to determine whether key components of the compliance program are operating effectively. Reviews should address compliance with laws governing:

- Kickback arrangements, the physician self-referral prohibition
- CPT/HCPCS & ICD-9 Coding
- Claim development and submission, and reimbursement
- Cost Reporting
- Marketing
- Internal Management Controls IHS rules and regulations
- Physician Contracts
- Vendor gratuities
- Excluded individuals and entities
- Quality of care monitoring
- Sarbanes-Oxley Act of 2002 (Corporate Governance)
- Compliance program testing and effectiveness

These reviews should address all risk areas, including external relationships and third party contractors, especially those with substantive exposure to governmental enforcement actions.

Types of reviews include:

- On-site visits
- Interviews with personnel involved in management, operations, coding, claim development and submission, patient care, and other related activities
- Reviews of medical and financial records and other source documents that support claims for reimbursement, as well as Medicare cost reports, such as denial logs
- Trend analysis, or longitudinal studies that seek positive or negative deviations in specific areas over a given period
- Patient satisfaction surveys and patient complaint logs

### **8.9.3 Auditing Activities**

Additionally, audits should inquire into compliance with specific rules and policies that have been the focus of particular attention on the part of the Medicare fiscal intermediaries or carriers and law enforcement, as evidenced by OIG Special Fraud Alerts, OIG Audits and Evaluations, and law enforcement initiatives. Examples of audits include:

- Observation services
- Medicare 3-day window
- Co-payment collections, claims denials
- Medicare secondary payer billing
- Department specific audits, such as
  - Admission review,
  - Pharmacy billing, distribution, and internal controls,
  - clinical chart
- HIPAA Privacy and Information Security audits, such as
  - Use and disclosure of protected health information (PHI),
  - Employee access to PHI,
  - Network security review

- Physician practice, including,
  - Outpatient rehabilitation documentation,
  - Medical staff credentialing and privileging
- Financial audits, including
  - central billing office and payroll
  - financial detection and prevention of fraud
  - credit balances
  - bad debt write-offs
- Cost report audits, including
  - grants and gifts
  - hospital-based and Emergency Department physician payments
  - asset and accelerated depreciation

#### **8.9.4 Monitoring Activities**

Monitoring activities include sampling protocols to identify variations from an established baseline. Significant variations from the baseline should trigger an inquiry to determine the cause. If the variation is the result of program deficiencies, prompt steps should be taken to correct problems due to program deficiencies, flawed policies and procedures, or a misunderstanding of or known violation of rules, regulations, or procedures.

For example, any overpayments discovered that are the result of such problems should be returned promptly to the affected payer, with appropriate documentation and a thorough explanation of the refund.