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Corporate Compliance

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The Federal Sentencing Guidelines were developed such that "sanctions imposed on organizations and their agents, taken together, will provide just punishment, adequate deterrents and incentives for organizations to maintain internal mechanisms for preventing, detecting and reporting criminal conduct". A corporate compliance program is the type of internal mechanism contemplated by the Sentencing Guidelines. The incentive for the adoption of a corporate compliance program is that an organization with "an effective [compliance] program that turns itself in upon discovering a violation and cooperates with the prosecution and has no involvement with high level officials in the offense may earn up to a 95% reduction in the penalty associated with the violation." Penalties include jail time for individuals, stiff fines for organizations, as well as possible exclusion from the Medicare and Medicaid programs.

Though several industries (banking, chemicals and government defense contractors) have had corporate compliance programs for some time, hospital systems, home health agencies and multi-specialty physician groups are struggling to put such programs in place. For example, during the last year, the United States Department of Justice sent letters to numerous Texas hospitals concerning Medicare laboratory claims which may have been "unbundled", doubled billed or improperly submitted and improper claims submitted for services rendered within 72 hours of hospitalization, which point out the need for effective corporate compliance programs. The DOJ letters seek to impose only civil penalties. Settlement of these claims has no effect upon any criminal penalties which may be asserted by the Justice Department.

In response to pressure from the healthcare industry, both the DOJ and OIG recently issued memorandums providing guidelines for False Claims Act suits. The OIG's guidelines, in the form of a memorandum to OIG staff, state that the OIG will establish minimum thresholds of either a monetary sum or a percentage error rate for referral of providers to the DOJ or other appropriate enforcement agency. The thresholds will vary from project to project, and if a provider falls under the established threshold, the provider will merely be referred for overpayment recoupment. In its guidance, the DOJ refused to adopt a minimum threshold standard and instead outlined predicates for determining if a false claim exists and if the provider knowingly submitted a false claim. These factors include whether the provider was given notice of the rule or policy involved, the clarity of the rule, whether the provider sought guidance from HCFA regarding the rule, and whether the provider has an "effective" compliance plan in place, which it is adhering to.

Developing a Compliance Program

It is extremely important that a compliance plan be tailored for a specific organization. There are numerous firms making a "cottage industry" out of providing prepackaged compliance plans to organizations. It is problematic whether these plans, which have not been developed by and for a specific organization, will be seen as sufficiently "effective" to provide relief from the Sentencing Guidelines or civil penalties asserted by the Office of Inspector General and Justice Department.

On February 12, 1998, the Office of Inspector General (OIG) issued Compliance Program Guidance for Hospitals to assist in developing effective compliance programs. In addition, this guidance revealed the elements on which OIG and the Department of Justice (DOJ) base their judgments with regard to reasonable efforts taken by management to avoid and detect any misbehavior that occurs in their operations.

The guidelines set forth seven core elements of an effective compliance plan:

1. Written standards of conduct for employees and written policies and procedures which promote the hospital's commitment to compliance and address specific areas of potential fraud;
2. The designation of a chief compliance officer and other appropriate bodies such as a corporate compliance committee;
3. The development and implementation of regular, effective education and training programs;
4. The maintenance of a process, such as a hotline, to receive complaints and adoption of procedures to protect the anonymity of complaints and to protect whistle blowers from retaliations;
5. The development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or federal health care program requirements;
6. The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem areas; and
7. The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

In addition to the compliance guidance for hospitals, on August 4, 1998, the OIG issued revised guidance for clinical laboratories as well as guidance relating specifically to home health agencies. The guidance for home health agencies is similar to the hospital compliance guidance. Compliance guidance for third party billing agencies is expected out this fall and the OIG is about to begin the process of creating guidance for DME companies, the managed care industry and third party billers. For the first time, the OIG will solicit comments regarding the guidance for DME companies.

The compliance program guidance for hospitals describes the appropriate organization officer to be the Chief Compliance Officer. The individual should be responsible for developing, overseeing, and monitoring the compliance program including the drafting of compliance policies and standards, oversee and monitor the company's compliance activities, have sufficient authority to undertake and comply with these responsibilities, have open access to senior management and the governing body of the organization and develop and distribute to the appropriate individuals all written compliance policies and procedures. In addition, the corporate compliance officer is responsible for (i) periodically revising the program in light of changes in the needs of the organization, laws, or governmental policies; (ii) developing and coordinating training programs; (iii) ensuring that independent contractors and agents of the hospital are aware of the requirements of the compliance program; (iv) coordinating personnel issues with the hospital's Human Resources office; and (v) independently investigating and acting on matters related to compliance. It may be advisable that the chief compliance officer not be the organization's in-house counsel so that the risk of losing the attorney/client privilege is minimized when noncompliance is uncovered. The OIG Compliance Guidance recommends that an organization have a compliance committee to advise the compliance officer and assist in the implementation of the compliance program.

The guidance spells out eighteen special areas of concern to the OIG which have been the subject of administrative proceedings, investigations and prosecutions under the False Claims Act. They are:

1. Billing for items or services not actually rendered;
2. Providing medically unnecessary services;
3. Upcoding;
4. Diagnoses related group ("DRG") creep;
5. Outpatient services rendered in connection with inpatient stays;
6. Teaching physician and resident requirements for teaching hospitals;

7. Duplicate billing;
8. False cost reports;
9. Unbundling;
10. Billing for discharge in lieu of transfer;
11. Patients' freedom of choice (particularly when hospital discharge planners refer patients to home health agencies, DME suppliers or for long term care and rehabilitation);
12. Failure to refund credit balances to Medicare and other federal programs;
13. Hospital incentives that violate the anti-kickback statute or other laws and regulations (including excessive payment for medical directorships, free or below market rents or fees for administrative services, interest-free loans and excessive payment for intangible assets in physician practice acquisitions);
14. Joint ventures;
15. Financial arrangements between hospitals and hospital-based physicians (such as compensating physicians for less than the fair market value of their services; requiring them to donate equipment or pay excessive charges for billing services);
16. The Stark physician self-referral law;
17. Knowing failure to provide covered services or necessary care to HMO members; and
18. Patient dumping.

The guidance advises hospitals to review at least annually whether bad debts were reported properly to Medicare to make sure the hospital has not claimed as bad debt "any routinely waived Medicare copayments and deductibles."

Implementation

In the planning and implementation of a corporate responsibility program practical common sense systems must be developed. The organization must develop and focus on the most important and potentially dangerous issues for the organization and not just those that are generally important in the industry. The identification and assessment of compliance and ethics risks must be teamed with recommendations for monitoring and mitigating specific risk areas as well as measuring the performance of the plan.

Any methodology associated with the development and implementation of a corporate responsibility plan must emphasize what will work and avoid creating new administrative burdens. The development of any plan must begin by determining standards identifying the values and ethics that are important to the organization and identify the most significant sources of risk to the organization.

The risk analysis must include a review of the organizational structure, major activities and major business relationships. A diagnostic review of each of the risk areas identified should include the following procedures:

1. Interviews with knowledgeable individuals concerning the scope of transactions regularly entered into by the organization, the procedures followed by the organization and the nature of available data;
2. Review of typical documents prepared in connection with each type of transaction;
3. The review of billing, cost, tax, and accounting reports generated by the organization; and,
4. A review of a small sample of typical transactions following them through the organization's reporting system.

A successful compliance program should require thorough monitoring, including periodic audits, of its implementation and regular reporting to senior executives and members of the board of

directors. At a minimum, a compliance audit should include on-site visits, interviews with personnel involved in management, operations, billing, sales, marketing and other related activities, reviews of written materials and documents used by the organization and trend analysis studies. Reports of the audits should be prepared and submitted to the Chief Compliance Officer and the Board of Directors to insure that management is aware of the results and can take whatever steps necessary to correct past problems and deter them from occurring. Audits or other analytical reports should specifically identify areas where corrective actions are needed. Subsequent audits or studies may be advisable to ensure that recommended corrective actions have been implemented and are successful.

The organization may utilize internal personnel to conduct the audit or may employ an outside consulting firm. If an outside auditor is used, the organization should consider having its outside legal counsel employ the auditor in order to preserve the attorney-client privilege.

The initial audit, whether conducted by internal or external auditors, is generally conducted in phases. A first phase may consist of an assessment of the billing risks, including evaluating the charge structure; reviewing CPT and UB-92 code assignment, pricing, high volume procedures, charge explosion or charge linkage reports to assess coding accuracy; comparing coding to the 1998 CPT coding manual; interviewing department representatives; ongoing education of staff; and review a sample of UB-92 forms (a minimum of twenty five forms is recommended). The first phase may also include a benchmark analysis including a DRG study to identify unusual billing patterns, since the OIG has access to this information.

An analysis of PPS, home care, DME, SNF and ASC billing as well as compliance with the three day payment window rules should also be conducted. Policies and patient account records may be reviewed. If the facility is a teaching facility, a review of a sample of professional line item services should be performed for teaching physician documentation. The results of the initial phase should be reported by the auditors to only designated personnel within the organization.

Compliance programs should include written policy statements setting forth degrees of disciplinary action that can be imposed upon employees for failing to comply with the company's code of conduct, policies and the law including failing to report suspected noncompliance. The program must be consistently enforced and the disciplinary standards should be disseminated to all employees. Corrective and disciplinary action must be taken against individuals who fail to comply with the compliance policies.

All employees should be educated regarding the compliance program. The training should include an overview of the fraud and abuse laws as applicable to the employee's position, the general components of the compliance program and each employee's obligation under the program. Such training should be required on a periodic basis and the failure of an employee to attend training should result in disciplinary action. The OIG Compliance Guidance further recommends that the organization require independent contractors including physicians with staff privileges to attend training sessions. The compliance officer should document all training sessions which should involve the use of interactive teaching methods. (The compliance guidance for home health further recommends that employees be asked to sign a statement certifying they have received, read, and understood the standards of conduct at the time they are hired and each time standards are updated or new standards are issued.)

An open line of communication between the Compliance Officer and his or her staff should be created and an open-door non-retribution policy should be established and made available to all employees to encourage communication. The establishment of a "hotline" for employees to report suspected fraud or compliance program violations may be advisable. Regardless of the type of communication, the compliance officer should maintain a log detailing each report received as part of the complaint program as well as describing the nature of any investigation and the results. Although the organization should strive to maintain the confidentiality of an employee's identity, it should clearly communicate to all employees that there may be a point where the

individual's identity must be revealed, for example, when governmental authorities become involved. Anonymity should never be promised.

The organization must evaluate protocols for investigating alleged or suspected fraudulent, illegal, or unethical activities. The organization should ensure that it has protocols in place to respond to allegations or suspicious activity including who is informed, who investigates, what form does the investigation take, and what happens with the results. No one line of defense can provide complete assurance as to compliance and ethics, instead it is the combination of properly identified and operating risk mitigators that addresses the organizations compliance and ethics risks.

These steps, although seeming to create additional administrative duties, are far less burdensome than a Compliance Plan or corporate integrity program which may be imposed by OIG or DOJ in settlement of a finding of wrongdoing. Furthermore, most of the requirements are designed to prevent fraud before it happens or at least to make management aware of the problems before a health care provider's continued viability is put at risk by taking away an organization's ability to provide services to recipients of federal funds.

Sample Methodology

Much of what is to be included in a compliance plan is "counter intuitive" - physicians and hospital personnel have been told to look for ways to maximize profits in a market where returns are declining.

No internal logic of many of the anti-kickback and Starke laws.

Why have a corporate responsibility plan? Most clients say it is too expensive, creates another level of bureaucracy and is ultimately unnecessary.

- Sentencing guidelines if a False Claims Act action is brought against the provider
- Indications that a compliance program will be a condition of participation in Medicare, Medicaid and other federal and state programs
- Provides a systematic means for providers to educate its staff and monitor compliance with applicable laws, rules and regulations.

Increased enforcement activities of the federal and state regulators:

- False claims act notices from the Department of Justice dealing with the 72-hour payment and lab unbundling issues. (Though now in the investigation of hospitals for possibly miscoding Pneumonia, the letter came from the Texas Medical Foundation - a kinder gentler method, though the findings will most likely be turned over to HCFA and the Dept. Of Justice.
- Increased funding for the DOJ and OIG. Expenditures for enforcement have reportedly returned \$1.00 for every \$.10 expended.

Not everyone in the healthcare business has an interest or the money to implement what the government considers to be an effective compliance plan:

- Some with an entrepreneurial bent don't need to be in a regulated industry. Until recently the enforcement by the government has been spotty in dealing with payment issues. Enforcement has tended to focus on patient abuse.
- The recent expulsion from the Medicare program of 80 community psychiatric centers (see sheet for costs).

- Rural healthcare providers and home health agencies. Difficulty of training workers with little education and with a high turnover.
- Indictment of attorneys in Kansas City for allegedly aiding and abetting a kickback scheme.

The banking industry spends 12% on oversight and integrity of its programs compared to 2% for hospitals. Until recent events, regulatory initiatives have focused on patient care - especially in nursing homes.