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Establishing an Effective Compliance Plan

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I. Introduction

Compliance with the complicated web of statutes and regulations governing federal and state programs is essential for all health care organizations. The penalties resulting from non-compliance and aggressive enforcement activities threaten all providers who participate in federal and state health care programs. The government is especially concerned with fraud and abuse in the health care payment system and has launched several major investigative initiatives directed at deterring excessive payments that can result from overcharges, unnecessary services and control of referrals. Violations of these requirements can result in fines, negative publicity, exclusion from programs and criminal prosecution. One of the best defenses against such consequences is a compliance plan.

II. Definition of a Compliance Plan

In light of the numerous laws and regulations affecting health care providers and the increased focus on fraud and abuse in the health care field, hospitals and other health care entities should consider implementing a compliance plan. A compliance plan can be broadly defined as "a comprehensive strategy to ensure that the organization consistently complies with the applicable laws relating to its activities and the delivery of health care." Thus, it is more than a broad policy which relates an organization's intent to follow the law and urges legal and ethical conduct by its employees. It is instead a strategy to ensure that an organization consistently complies with the applicable laws relating to its business activities and contains mechanisms for oversight and internal enforcement of compliance. A formally adopted compliance plan should reduce the chances of an organization violating laws and provide internal reporting and follow-up procedures.

III. Basic Elements of a Compliance Plan

A compliance plan has two basic elements: structural and substantive. The structural element consists of the framework and essential elements of the program and is generally the same regardless of the business or industry or the applicable area(s) of law. The substantive element is the specific body of law (fraud and abuse, tax, antitrust, environmental) with which the organization is trying to ensure compliance.

Neither element can be said to be more important than the other. In order to create an effective compliance plan, an organization must understand the regulatory environment in which it operates. For example, for a health care provider to comply with the fraud and abuse laws, it must understand the claims process and make sure that employees understand how the Medicare and Medicaid laws affect their job functions and know which practices are prohibited. Employees must also be made aware of their obligation to be active participants in the organization's effort to comply with the laws and to participate in the procedures designed to identify non-compliance.

IV. Federal Fraud and Abuse Laws

A. False Claims Violations

1. Criminal False Claims for Medical Services

An individual may be held criminally liable for the following prohibited acts:

a) knowingly and willfully making or causing to be made any false statement in an application for benefits or payment under a Federal or State health care program or knowingly and willfully using any such statement to determine rights to benefits or payment;

b) failing to disclose knowledge of any event affecting a right to benefits or payment with fraudulent intent;

c) knowingly and willfully converting any benefit or payment to the use of a person other than for whom it was intended; or

d) presenting a claim for payment for physician's services knowing that the person who furnished the service was not a licensed physician. (1)

A person who commits any of these acts in connection with that person's providing covered items or services is guilty of a felony and is subject to a fine of up to \$25,000 and/or a prison sentence of no more than five years. In the case of a false statement, concealment, failure to disclose or conversion by any other person, that person is guilty of a misdemeanor and may be fined up to \$10,000 and/or imprisoned for up to one year.

2. Civil Penalties for Improper Claims for Medical Services

Provisions in the Social Security Act impose civil penalties for knowingly presenting or giving a claim or information which the person knows or should know is improper or false. (2) There is no requirement of specific intent to defraud the government; deliberate indifference or reckless disregard is sufficient. Improperly filed claims for medical services furnished under government programs can subject a person to a civil money penalty of up to \$10,000 per item or service, plus an assessment of up to three times the amount claimed for each item or service.

3. False Claims Act

The False Claims Act prohibits knowingly making false statements to the United States Government or causing such statements to be made in order to obtain payment on a false or fraudulent claim or otherwise causing a false claim to be filed. (3) A claim is any request or demand for money or property if the U.S. Government provides or will reimburse any portion of the money or property. (4) The False Claims Act defines "knowingly" as any of the following: 1) having actual knowledge of the information; 2) acting in deliberate ignorance of the truth or falsity of the information; or 3) acting in reckless disregard of the truth or falsity of the information. (5) No proof of specific intent to defraud is required.

Any person who violates the False Claims Act is liable to the federal government for a civil penalty of at least \$5,000 but no more than \$10,000, plus three (3) times the amount of damages sustained by the Government by the person's act. If the person informs the Government within thirty days of learning of the violation (but before learning of any Government investigation and before any action has been taken by the Government) and cooperates fully with any investigation, then the court may assess double damages instead of treble.

4. Qui Tam Actions

A private person may bring a civil action under the False Claims Act for herself and for the United States Government. (6) Such an action, known as a qui tam suit, is brought in the name of the Government and may be dismissed only if the court and the Attorney General give written consent to the dismissal and their reasons for consenting. A copy of the complaint and written disclosure of all material evidence and information possessed by the person must be served on the Government. (7) The complaint is filed in camera, remains under seal for at least sixty (60) days and will not be served on the defendant until the court orders service. The Government may move for extension of the time during which the complaint remains under seal. Before the expiration of the 60-day period or any extensions, the Government must either proceed with and conduct the action or notify the court it declines to take over the action, in which case the person bringing the action has the right to continue it.

If the Government proceeds with the action, the person bringing the action has the right to continue as a party, but the Government has primary responsibility for prosecuting the action and is not bound by the person. (8) The Government may dismiss or settle the action without the person's consent, and the court may, in its discretion, impose limitations on the person's participation. (9) If the Government proceeds with the action, the person shall receive at least 15% but not more than 25% of the proceeds of the action or settlement of the claim. (10) Any such person shall also receive attorneys' fees and costs incurred. However, if the court finds that the person bringing the action was the person who planned and initiated the violation, the court may reduce his or her share of the proceeds. (11)

If the Government elects not to proceed with the action, the person has the right to continue the action; however, the court may permit the Government to intervene at a later date. (12) If the Government

does not proceed with the action, the person bringing the action or settling the claim will receive an amount between 25% and 30% of the proceeds of the action or settlement. (13) Such a person will also receive attorneys' fees and costs incurred. If the court finds that the claim of the person bringing the action (without Government) was clearly frivolous or vexatious or brought primarily for harassment purposes and the defendant prevails, the court may award the defendant its attorneys' fees and expenses. (14)

B. Anti-Kickback Provisions

Federal law prohibits knowingly and willfully soliciting or receiving any payment in return for referring an individual for any item or service paid for in whole or part under Medicare or Medicaid. (15) The law also forbids payment in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of anything for which Medicare or Medicaid will pay. Taking or asking for a kickback is a felony; offenders face a fine of no more than \$25,000 or imprisonment of no more than five (5) years. Further, anyone who offers or pays any such illegal remuneration also commits a felony punishable by a fine of no more than \$25,000 or a five-year sentence. Penalties for illegal remunerations require knowledge and willfulness in soliciting, offering, receiving or paying any kickback, but there is no required intent to defraud the government.

Exceptions to the act include certain disclosed price discounts, bona fide employee compensation, group purchasing arrangements, and waiver of coinsurance by a federally qualified health care center. (16) Published safe harbors include specified investment interests, leases of space and equipment, and personal services and management contracts. (17)

C. Self-Referral Prohibitions: Stark I & II

The original physician self-referral law, passed by Congress in 1989 and now known as "Stark I," prohibits a physician with a financial relationship with an entity that furnishes clinical laboratory services (or a physician with an immediate family member who has such a relationship) from making a referral to that entity for clinical laboratory services for which Medicare would pay. In August 1993, Congress significantly amended the Stark Law. These amendments, which have become known as "Stark II," expand the Stark I ban on self-referral to include referrals of Medicare and Medicaid for "designated health services."

If a physician or any of her immediate family members has a financial relationship with an entity, the physician may not make a referral to that entity for the furnishing of designated health services to be paid for under Medicare or Medicaid. (18) The entity itself may not present any claim for designated health services furnished as a result of such a referral. A "financial relationship with an entity" is 1) an ownership or investment interest in the entity or 2) a compensation arrangement between the physician and the entity. (19) "Designated health services" means any of the following items or services:

1. clinical laboratory services
2. physical therapy services
3. occupational therapy services
4. radiology or other diagnostic services
5. durable medical equipment
6. parenteral and enteral nutrients, equipment and supplies
7. prosthetics, orthotics and prosthetic devices
8. home health services
9. outpatient prescription drugs
10. inpatient and outpatient hospital services. (20)

The prohibition does not apply to physician services provided by another physician in the same group practice; to in-office ancillary services; nor to pre-paid plans. (21) Exceptions to the ownership or investment prohibition are provided for certain public securities, interests in a hospital, and rural providers. (22) Exceptions to the compensation arrangement restriction include the rental of office space or equipment; bona fide employment relationships; personal service arrangements, including certain physician incentive plans; remuneration unrelated to the provision of designated health services; physician recruitment by a hospital; isolated transactions; certain group practice arrangements with a hospital; and payments by a physician for items and services. (23)

No payment may be made for a designated health service which is provided as a result of a self-referral; further, any payments collected on an improper claim must be refunded on a timely basis. (24) Any person who presents a claim for a service which that person knows or should know is a service resulting from a self-referral is subject to a fine of up to \$15,000 for each such service. (25) Any physician or entity that enters into an arrangement which the physician or entity knows or should know has a principal purpose of assuring prohibited referrals is subject to a fine of no more than \$100,000 for each such arrangement. (26) Anyone who is required but fails to meet the reporting requirements for ownership arrangements is subject to a civil penalty of up to \$10,000 for each day for which reporting was required. (27)

D. The Health Insurance Portability and Accountability Act of 1996

Through the enactment of Title II of the Health Insurance Portability and Accountability Act of 1996, the federal government has increased and strengthened its enforcement efforts in the area of health care fraud and abuse.

The Act created four new initiatives addressing fraud in government medical service programs:

1. Fraud and Abuse Control Program -- This program, to be run by the Department of Justice and the Office of the Inspector General, will focus on investigation and enforcement of health care fraud and abuse.

2. Medicare Integrity Program -- The Act authorized the Department of Health and Human Services to contract with private companies to detect fraud and abuse, to conduct audits, and to offer provider education.

3. Beneficiary Incentive Program -- This program will encourage beneficiaries to report suspected Medicare fraud or abuse; individuals who provide information leading to the recovery of at least \$100 by the Department of Justice or HHS may be paid a portion of that recovery.

4. Health Care Fraud and Abuse Data Collection Program -- HHS will run a program to be coordinated with the National Practitioner Data Bank for reporting final adverse actions taken against a health care practitioner, provider or supplier.

The Act added the following individuals and entities to the list of persons who are subject to civil penalties for improperly filed health care claims:

1. Any individual who, at the time of a violation, is excluded from participation in a Federal or State health care program, and retains a direct or indirect ownership or control interest in a participating entity and knows or should know of the violation, or is an officer or managing employee of such an entity;

2. Any individual or entity which offers or gives remuneration to any person eligible for benefits that he or she knows or should know is likely to influence the beneficiary to order or receive any item or service from a particular provider;

3. Any individual or entity who engages in the practice of "upcoming"-- presenting a claim based on a code that the person knows or should know will result in greater payment to the person that the code which is actually applicable.

Further, any physician who provides false certification for home health services knowing that the eligibility requirements have not been met is subject to a civil monetary penalty of the greater of \$5,000 or three times the amount of payments for home health services made pursuant to such certification.

The Act also added several federal crimes to Title 18 of the United States Code:

1. Health care fraud is knowingly and willfully executing or attempting a scheme to defraud any health care benefit program or to obtain by false pretenses any of the money or property of a health care benefit program. Health care fraud is punishable by a fine and/or sentence of up to 10 years; if the violation results in serious bodily injury, then the sentence can be increased to up to 20 years, and if the violation results in death, then the person can receive up to a life sentence.

2. Theft or embezzlement in connection with health care consists of knowingly and willfully embezzling, stealing or otherwise converting or intentionally misapplying any money, property or assets of a health care benefit program. It is punishable by a fine and/or up to 10 years in prison; however, if the value does not exceed \$100, then the prison sentence can be no more than one year.

3. The crime of making false statements relating to health care matters consists of knowingly and willfully falsifying, concealing or covering up a material fact, or making any materially false or fraudulent statements or representations, or using any false writing or document knowing the same to contain a

false statement or entry, in connection with the delivery of or payment for health care benefits, items or services. Any person convicted of this crime may be fined and/or sentenced to up to 5 years in prison.

4. Obstruction of criminal investigations of health care offenses is willfully obstructing, preventing, misleading or delaying the communication of information relating to a violation of a Federal health care offense to a criminal investigator and is punishable by a fine and/or up to 5 years in prison.

The Act also allows the government to freeze the assets of a person who is committing or about to commit a Federal health care offense.

The Health Insurance Portability and Accountability Act constitutes a meaningful increase in the resources and penalties available for use in investigating and carrying out fraud prosecutions. As such, the Act indicates the federal government's dedication to the enforcement of health care fraud and abuse laws. This heightened priority makes a compliance plan even more of a necessity for all health care organizations.

V. Benefits of a Compliance Plan

A. Reduce the likelihood of civil or criminal wrongdoing.

A compliance plan establishes a structure which encourages employees to report concerns internally rather than externally; this in turn reduces the risk of government investigation. As a result of the implementation of a compliance plan, the organization will be able to identify and correct non-compliant conduct before it is identified by regulators. The organization will also have a mechanism for quickly and efficiently disseminating information regarding changes in relevant regulation.

B. Reduce the likelihood of qui tam suits

Even if the government does not pursue an action against an organization, any individual may institute a qui tam suit against the organization under the False Claims Act. (28) Depending on the circumstances, a qui tam relator can recover between fifteen and thirty percent of the damages awarded plus reasonable expenses and attorney fees. (29) In order to bring a successful qui tam action, however, the relator must be the first to reveal the wrongdoing to the government. This is less likely to occur when the organization has a system for uncovering and reporting corporate wrongdoing.

C. Reduce the penalties which the organization would face if there were any wrongdoing.

1. Prosecutorial discretion

The existence of a compliance plan may convince a prosecutor not to indict an entity which was the victim of unscrupulous employees. If an offense occurred despite the existence of an effective compliance plan, a prosecutor may determine that prosecuting the organization will have little deterrent effect. Also, an entity which is the victim of an employee should not be viewed as being as culpable as an organization which does not have a compliance plan or which has ignored evidence of employee misconduct. If the organization has discovered and reported the offense on its own, such a report is evidence of the organization's good faith efforts to comply with the law.

2. Federal Sentencing Guidelines

a. Corporate entities may be held vicariously liable for the criminal conduct of employees who acted with an intent to benefit the corporation, even if the action is contrary to corporate policy or instructions. (30) Under the United States Sentencing Guidelines (Guidelines) for corporate entities, the "base fine" for a culpable corporation is multiplied by a "culpability score" which varies according to aggravating or mitigating factors such as the size of the corporation, the involvement or tolerance of corporate officers, and cooperation with the authorities. *However, corporations which have an "effective plan to prevent and detect violations of the law" are entitled to a reduction in their culpability score.*

b. The Guidelines do not specifically set out all of the actions required for a compliance plan to prevent and detect violations of the law. The determination of whether or not a plan is effective and appropriate depends in part on the organization's size, the nature of its business activities and its prior history of compliance problems. (31) The larger an organization is, the more formal the compliance plan should be. If the nature of the organization's business means that certain types of offenses are more likely to occur, management must have taken steps to prevent and detect those types of offenses. Recurrence

of the same or similar misconduct indicates that an organization might not have taken all reasonable steps to prevent such misconduct.

VI. An "Effective" Compliance Program

To qualify as an "effective" compliance program, a plan must be reasonably designed, implemented and enforced so that it will be generally effective in detecting and preventing criminal conduct. (32) While the Guidelines do not provide any details as to how organizations can meet this definition, the government has offered some guidance as to what will qualify. The Office of the Inspector General of the Department of Health and Human Services (OIG) has entered into corporate integrity agreements which implement the government's own compliance programs with health care entities alleged to have violated fraud and abuse laws. (33) The OIG also released in February 1997 the Model Compliance Plan for Clinical Laboratories, which provides specific guidelines as to compliance plans for clinical laboratories and is a source of guidance for other health care organizations. (34) The Model Compliance Plan for Clinical Laboratories is discussed in greater detail below. The OIG's future plans include developing model compliance programs for hospitals and managed care organizations.

The Guidelines themselves contain seven requirements that must be met in order to qualify as an effective compliance plan:

A. Compliance Standards and Procedures

"The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal conduct." (35)

1. The compliance plan must clearly identify the standards to which employees will be held and the types of conduct which the plan is intended to eliminate. A mere statement of intent to comply with the law is not enough.
2. The standards must clearly articulate to employees that they must make sure their conduct is consistent with the standards, that they should seek clarification when they are unsure, and that they should report suspected violations to the appropriate person.
3. The compliance standards may include generalized codes of conduct which apply to all employees and specific rules and procedures which relate to particular jobs.

B. Responsibility of High Level Personnel

"Specific individual(s) within high level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures." (36)

1. The Guidelines do not expressly require that an organization create a position such as "Compliance Officer" or "Director of Compliance," but the high level individual should be someone in a position to influence behavior and organization practices, including a director, an executive officer, an individual with substantial ownership interest or an individual in charge of a major business or functional unit of the organization. Basically, the person who has the power to control or administer the compliance plan must have the authority necessary to make the plan work.
2. The individual should be responsible and accountable for the organization's compliance activities, and compliance activities should be a material component of the person's job description and a basis for evaluation of job performance.

C. Employee Screening

"The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have know through the exercise of due diligence, had a propensity to engage in illegal activities." (37)

1. This requirement appears to impose a duty to conduct background checks on applicants for positions with substantial supervisory authority or substantial discretion within the organization. According to the Guidelines, whether an individual falls into one of the two categories will be determined on a case-

by-case basis. Most management personnel and many professionals, including physicians, would probably be included in one of the categories.

2. This requirement also seems to oblige the organization to remove employees who have shown a disregard for relevant program standards from positions of substantial authority or discretion.

3. The organization should exercise diligence in all hiring, particularly with respect to employees who will be preparing claims. Providers should avoid hiring individuals on the Office of the Inspector General's list of people excluded from the Medicare and Medicaid programs.

D. Monitoring and Auditing

"The organization must have taken reasonable steps to achieve compliance with the standards by utilizing monitoring and auditing systems reasonably designed to detect criminal conduct by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report criminal conduct by others within the organization without fear of retribution." (38)

1. The organization must use monitoring and auditing systems designed to detect criminal conduct by employees. Given the complexity of Medicare and Medicaid billing requirements, it is extremely difficult for an entity to audit itself adequately without a regular and systematic auditing program. Such a program should include a review of every part of the claim process from patient registration to submission of the claim to Medicare or Medicaid.

2. The compliance plan must also provide for a mechanism allowing employees to report suspected improper practices without fear of retribution or negative consequences. The plan should communicate to employees their right and obligation to report any such suspicions. The employee should have the opportunity to report suspected misconduct to either the employee's manager or the organization's counsel or audit staff. The Guidelines do not require special reporting hot lines or the right to anonymous reporting, but the organization must ensure that employees do not suffer any adverse consequences from reporting a concern in good faith.

3. The organization must respond promptly to the employee's report. Any failure to investigate a complaint calls into question the effectiveness of the compliance plan. If employees believe that the organization is serious about investigating reports of misconduct, then employees will be more likely to allow the organization to resolve any problem internally. If the organization fails to respond, it is possible that an employee will report the suspected violation to the government. A prompt response to employee complaints sends a message to employees and to enforcement officials that the organization takes its compliance obligation seriously.

E. Education and Training

"The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required." (39)

1. A compliance plan must include education programs designed to train and inform employees whose job functions affect compliance by the organization. Mere statements that employees must comply with the law are inadequate and useless if the organization has never explained to the employees what the law is and how it applies to the employees' work.

2. Education and training should include:

a. an overview of the relevant regulatory scheme;

b. an explanation of the compliance plan and each employee's obligation to participate in compliance;

and

c. extensive education specific to each employee's job requirement and the applicable federal and state laws and regulations.

3. Explanation of what the law requires should be communicated in a practical manner which the employee understands and which applies to the context of the employee's job.

4. Possible techniques for the education program include compliance manuals which explain procedures to be followed to ensure compliance, internal and external experts, oral presentations, videos, and testing.

5. Educational programs should include all physicians and all employees involved in the preparation of Medicare and Medicaid claims or other areas on which compliance is focused.

6. The organization should carefully document its training activities and keep records of attendance at educational sessions.

F. Response and Prevention

"After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses -- including any necessary modifications to its program to prevent and detect violations of law." (40)

1. The organization must take reasonable steps to change the organization's procedures and practices so that the likelihood of a problem recurring is reduced. The organization could provide additional training for employees, modify billing systems or adjust applicable procedures. The entity should also take steps to "respond appropriately to the offense." Such steps could include voluntarily disclosing the problem to government officials and reimbursing for potential overpayments.

G. Enforcement and Discipline

"The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense. Adequate discipline of individuals responsible for an offense is a necessary component of enforcement; however, the form of discipline that will be appropriate will be case-specific." (41)

1. A written enforcement and discipline policy is very important. The compliance plan must include mechanisms to ensure that employees who violate compliance standards or program requirements are punished. The plan should also provided for the disciplining of employees who fail to report or investigate concerns which should have been apparent.

2. The inability of the organization to show that it has appropriately disciplined individuals calls into question the effectiveness of the compliance plan.

3. In addition, creation and operation of a compliance plan is an allowable Medicare and Medicaid cost and is tax deductible, unlike fines and penalties.

VII. The Model Compliance Plan for Clinical Laboratories

The Model Legal Compliance Plan for Clinical Laboratories was developed by the Office of Inspector General of the U. S. Department of Health and Human Services and published in February 1997. The purpose is "to supply guidance to health care providers that supply clinical laboratory testing services for Medicare and Medicaid beneficiaries as to the elements of a model compliance plan." A laboratory need not necessarily incorporate all elements, and one who does not fully adopt the Model Plan is not necessarily at a disadvantage under scrutiny of the OIG.

A. Features of the Model Plan

According to the Model Plan, a comprehensive compliance program should include "at a minimum":

- 1. The development and distribution of written policies that promote the laboratory's commitment to compliance and that address specific areas of potential fraud such as billing, marketing, and claims processing.** Such standards and policies should:
 - a. clearly delineate the policies of the lab with regard to fraud and adherence to federal guidelines and regulations;
 - b. ensure that claims are only submitted for services the lab *"has reason to believe are medically necessary"*; some guidance is given on how a lab can verify this through:
 - (1) using standardized requisition forms that document the need for the test;
 - (2) communicating regularly with physicians;
 - (3) requiring a Physician Acknowledgment for all customized profiles; and
 - (4) monitoring test utilization;

- c. ensure that claims for services submitted to Medicare are accurate and correctly identify the services ordered and performed;
- d. monitor existing standing orders to ensure their validity;
- e. ensure compliance with HHS OIG Fraud Alerts;
- f. require "honest, straightforward, fully informative and non-deceptive marketing";
- g. ensure that physicians are charged more for enhanced profiles, and that physicians are never charged at a rate below costs;
- h. ensure that all required records are created and maintained; and
- i. include promotion and adherence to compliance programs as an element in evaluating supervisors and managers

2. The designation of a chief compliance officer or other appropriate high level corporate structure or official who is charged with the responsibility of operating the compliance program.

The compliance officer should be responsible for developing the compliance policies and standards, overseeing and monitoring the organization's compliance activities, and achieving and maintaining compliance.

3. The development and offering of education and training programs to all employees.

Education in compliance and ethics for all employees, especially those involved in billing, sales, marketing, and specimen collection and/or test ordering should be required. The need for periodic continuing education should also be addressed. These educational efforts "should leave no doubt in the minds of employees and others" about the company's commitment to compliance.

4. The use of audits and/or other evaluation techniques to monitor compliance and ensure a reduction in identified problem areas. Quality assurance and zero tolerance of fraud and abuse should be the goal of the program, and "auditing is a good tool to use to reach that goal."

5. The development of a code of improper/illegal activities and the use of disciplinary action against employees who have violated internal compliance policies or applicable laws or who have engaged in wrongdoing.

6. The investigation and remediation of systemic and personnel problems. All reports of potential non-compliance must be promptly to determine whether a material violation has occurred. It is recommended that the laboratory give notice to the OIG within sixty (60) days of receipt of credible evidence that misconduct may have occurred. It is also suggested that employees suspected in engaging in misconduct should be removed from their positions and/or reassigned pending the outcome of the investigation.

7. The promotion of and adherence to compliance as an element of evaluating supervisors and managers.

8. The development of policies addressing the non-employment or retention of sanctioned individuals.

9. The maintenance of a hotline to receive complaints and the adoption of procedures to protect the anonymity of complainants. "An open line of communication between the compliance officer and his or her staff is critical." All reports should be allowed to be made confidentially and without fear of retribution. A hotline is suggested, but other means of reporting are acceptable.

10. The adoption of requirements applicable to record creation and retention.

VIII. Components of a Hospital's Compliance Plan

Because of the wide variation in the size, and thus the individual needs, of hospitals and the relatively new application of corporate compliance in the health care setting, little uniformity has arisen in hospital compliance programs. The Federal Sentencing Guidelines and the Model Compliance Program for

Clinical Laboratories can serve as a foundation on which to build the structural element of a compliance program for a hospital. However, a hospital's compliance program should not be limited to issues raised by its participation in federal and state health care programs. Hospitals are faced with a much broader framework of laws and regulations within which they must strive to operate. Therefore, the hospital's compliance program policy manual outlining the substantive components of a hospital's compliance program should address and make employees aware of the areas of concern that affect hospitals on a day-to-day basis. Some of these may be addressed elsewhere in the hospital's general policies and procedures, or perhaps in the employee handbook. Some of these elements may also be combined. For example, billing, illegal remuneration and patient referrals may be combined into a "fraud and abuse" section.

A. Billing and Claims for Payment

Because of the breadth and complexity of regulations governing billing and claims for payment and the severe consequences of non-compliance, this will be one of the most extensive and well-developed aspects of the compliance program. All employees and staff members who are in any way involved in the process of making a claim for payment, including billing clerks, medical records clerks (who ensure that charts are complete and the necessity for a procedure is documented), and health care practitioners, must be trained in the proper procedures for making a claim for payment. Dissemination of changes in the regulations, monitoring compliance, and internal auditing of claims are all important components of this part of a compliance program.

B. Payments and Illegal Remuneration

This section addresses the prohibitions and proscribed arrangements under the fraud and abuse and anti-kickback laws, including restrictions on tax-exempt organizations (if applicable).

C. Patient Referrals

In this section, the anti-kickback laws and the Stark prohibitions on self-referral are discussed.

D. Physician Recruitment

Again, the fraud and abuse and anti-kickback laws, the Stark law, IRS restrictions, and for public hospitals, restrictions on the expenditure of public funds and their implications on physician recruitment are discussed.

E. Antitrust

Some hospitals also have very extensive antitrust components of their compliance program. Discussions with competitors and physician credentialing/services should be addressed. Unfair and/or deceptive trade practices may also be part of this section or may be separate.

F. Physician Practice Acquisition

The application of the anti-kickback, the Stark law, and IRS restrictions should be addressed in the context of physician practice acquisitions.

G. Response to Investigation

In today's heightened regulatory environment, the hospital should have as part of its compliance program a clear policy on how hospital employees should respond to investigators or requests for information by regulatory agencies. The policy should contain a statement on whom to notify if an employee is contacted about an active investigation or if documents are requested and a statement on the hospital's policy on release documents.

H. Patient Transfers

This section should address issues implicated by the Emergency Medical Treatment and Active Labor Act, including providing an appropriate medical screening and the proper procedures for treating and/or discharging patients who present in an emergency medical condition. The requirements of a proper transfer should be outlined.

I. Confidentiality

Many hospitals have policies regarding the confidentiality of information. This section may merely refer to those policies, but maintaining the confidentiality of information should be a part of the hospital's overall compliance program.

J. Discrimination

To the extent not addressed elsewhere, this section should set forth the hospital's policy with respect to discrimination, both as to employees/staff members and patients.

K. Controlled Substances

Federal and state requirements with respect to the handling of controlled substances, including reporting requirements when a theft or loss is detected, should be addressed.

M. Reporting Requirements

This section is a catch-all section on the various reporting requirements of the hospital and its licensed employees. It addresses required reports of gunshot wounds, abuse or neglect of children and the elderly, communicable diseases, and reporting requirements of various licensing boards.

N. Waste Disposal and Environmental Issues

While the vast expanse of environmental laws and regulations is beyond the scope of a policy manual, employees should at least be aware that these laws exist (including the Clean Air Act, the Clean Water Act, the Resource Conservation and Recovery Act, and other federal laws) and should be charged with reporting or at least making further inquiry regarding releasing/disposing of hazardous substances. Employees should also be educated on the proper labeling and disposal of biohazardous material.

O. Fund Raising

Policies should be developed regarding how and by whom fund-raising activities can be undertaken, and the hospital should have a specific policy against the unauthorized use of the hospital's or an affiliated organization's (e.g., an auxiliary's or a foundation's) name in fund-raising activities.

P. Mental Health Services

Texas hospitals who provide mental health services, including detox services, must be aware of the Texas Treatment Facilities Marketing Practices Act.

Q. Federally Funded Grants

Any institution that receives grants from the federal government should educate employees on the requirements and restrictions involved, including accurate reporting and appropriate expenditures of funds.

IX. Implementation of a Compliance Plan

A. Identify the risk areas

A major part of the process is to identify the areas of the law and the risks which the compliance plan will address. A number of these areas are addressed above. Compliance plans must be specifically designed to meet an organization's particular needs and circumstances. Before developing compliance standards and procedures, the entity should conduct a compliance review to identify specific action areas, in conjunction with a legal review. An organization should not assume that it is currently complying with all applicable laws. Further, an entity should not assume that just because the government has not identified problems within the organization that such problems do not exist.

The organization should define its goal so that it is clear about the scope and objectives of the compliance plan. The organization should also evaluate any compliance plans or policies which it is currently using and determine how the existing policies fit into its compliance program.

B. Involve management

The organization needs to identify the people who are necessary participants to the creation and execution of the compliance plan. The Federal Sentencing Guidelines require high level oversight to have an effective compliance plan; this requirement could be met by having an officer responsible for the program who reports the entire process to a board-level committee. Further, a compliance plan will probably not be effective if it does not have management support or if the corporate climate does not hold individuals at every level of the chain of command accountable for their actions.

C. Protect the organization

The implementation of a compliance plan does include some risk. If the organization's plan is to be effective, it must include audits which will most likely uncover non-compliant behavior. The organization must decide whether it has any obligation, legal or otherwise, to disclose any non-compliant conduct uncovered during its own audit.

In order to take advantage of the attorney-client privilege whenever possible, the implementation process should either be managed by or include significant input from the organization's legal counsel.

D. Involve key personnel

Since creation of an effective plan requires an understanding of how the system actually operates, the process will require the participation of employees involved in the claims process, including nurse auditors, financial auditors, individuals with billing and coding expertise and information systems personnel.

E. Basic elements of implementation

1. Development of compliance policies. Once the areas of risk are identified, the hospital, if it has not already done so, must adopt a statement of the hospital's policy in that area. The policy should outline the legal requirements for that area of risk and should contain a brief statement of the expected conduct with respect to that issue.

2. Appoint compliance officer / Develop compliance structure. Regardless of whether the hospital has a compliance officer, compliance committee, or some other mechanism to implement and monitor the program, this design should be in place early in the process of developing the program so that the individuals who are responsible for running the program will have some input into how it is structured.

3. Conduct baseline audits. The only way an organization will know what it is facing in terms of becoming compliant is to evaluate its current practices and the education/knowledge level of its employees.

4. Develop the hospital's approach to ensure compliance. This is where the most variation will occur from hospital to hospital and compliance program to compliance program. Each hospital will have to assess its own needs and develop its own methods for educating its employees and ensuring continued compliance.

5. Educate employees/contractors on the existence of the compliance program and the policies. In order for an employee to be held responsible for complying with the elements of a compliance program, the employee must be aware of the existence of the program and the commitment of the organization. Each employee should sign an acknowledgment that he or she is aware of the program and the employee's role and responsibilities with respect to maintaining compliance *and reporting noncompliance*.

6. Conduct education sessions and periodic audits as needed. Each employee must be educated on the areas of risk implicated by his or her functions at the hospital. The extent of initial education obviously will vary according to the knowledge level of the individual employees. New employees must be oriented on both the existence of the program and their role in it, as well as the specific substantive areas.

7. As needed, follow up on reports of noncompliance, as well as disciplinary action for employees who contribute to noncompliance or who fail to recognize or report noncompliance.

Endnotes

1. 42 U.S.C. § 1320a-7b(a).
2. 42 U.S.C. § 1320a-7a(a).
3. 31 U.S.C. § 3729.
4. 31 U.S.C. § 3729(c).
5. 31 U.S.C. § 3729(b).
6. 31 U.S.C. § 3730(b)(1).
7. 31 U.S.C. § 3730(b)(2).
8. 31 U.S.C. § 3730(c)(1).
9. 31 U.S.C. § 3730(c)(2)(A).
10. 31 U.S.C. § 3730(d)(1).
11. 31 U.S.C. § 3730(d)(3).
12. 31 U.S.C. § 3730(c)(3).
13. 31 U.S.C. § 3730(d)(2).
14. 31 U.S.C. § 3730(d)(4).
15. 42 U.S.C. § 1320a-7b(b).
16. 42 U.S.C. § 1320a-7b(b)(3).
17. 42 C.F.R. § 1001.952.
18. 42 U.S.C. § 1395nn(a)(1).
19. 42 U.S.C. § 1395nn(a)(2).
20. 42 U.S.C. § 1395nn(h)(6)(A)-(K).
21. 42 U.S.C. § 1395nn(b)(1)-(3).
22. 42 U.S.C. § 1395nn(c)-(d).
23. 42 U.S.C. § 1395nn(e)(1)-(7).
24. 42 U.S.C. § 1395nn(g)(1)-(2).
25. 42 U.S.C. § 1395nn(g)(3).
26. 42 U.S.C. § 1395nn(g)(4).
27. 42 U.S.C. § 1395nn(g)(5).
28. 31 U.S.C. § 3730(b).
29. 31 U.S.C. § 3730(d)(1)-(2).
30. United States v. Hilton Hotel Corp., 467 F.2d 1000 (9th Cir. 1972), cert. denied, 409 U.S. 1125 (1973).
31. Federal Sentencing Guidelines Manual § 8A1.3(k)(7) [hereinafter Guidelines Manual].
32. Guidelines Manual § 8A1.2(k).

33. The HHS/OIG World Wide Web Site offers beneficial information, including Special Fraud Alerts, Office of Enforcement & Compliance Reports, and Advisory Opinion Information. The home page for the HHS/OIG is at www.dhhs.gov/progorg/oig.

34. The full text of the Clinical Laboratory Model Compliance Plan is available on the Internet at www.os.dhhs.gov/progorg/oig/cpcl.html.

35. Guidelines Manual § 8A1.2(k)(1).

36. Guidelines Manual § 8A1.2(k)(2).

37. Guidelines Manual § 8A1.2(k)(3).

38. Guidelines Manual § 8A1.2(k)(4).

39. Guidelines Manual § 8A1.2(k)(5).

40. Guidelines Manual § 8A1.2(k)(6).

41. Guidelines Manual § 8A1.2(k)(7).