OPEN MINDS On-Line News

July 8, 2002

Feature

Keys to Developing a Regulatory Compliance Program

A health care compliance plan is a formal operational program. It has specific policies, procedures and staffing designed to ensure that a healthcare organization prevents and detects violations of the law in its practice of doing business. In the past, only large healthcare provider organizations (such as hospitals, major clinical laboratories and skilled nursing facility chains) had established formal healthcare compliance programs. Now it is essential for all providers - large and small, for-profit and not-for-profit.

Executives of behavioral health and social service provider organizations have always been responsible for ensuring that they conduct their businesses in accordance with all applicable federal, state and local laws, rules and regulations, as well as with the program requirements of federal and state-sponsored health plans (such as Medicare and Medicaid). Since Congress passed the Health Insurance Portability and Accountability Act of 1996 (HIPAA), however, the U.S. Department of Health and Human Services Office of Inspector General (OIG) has been mandated to establish expanded programs for detecting healthcare fraud and abuse, as well as encouraging the public to report it. Most importantly, HIPAA also broadened the definition of "knowing and wilfull conduct" in regard to civil provision of the Social Security Act to include acts of "deliberate ignorance" by providers with respect to information and regulation.

What does this mean for your organization? Essentially, it means that even unintentional violations of the law (most commonly incorrect billing practices) can result in serious penalties. Thus, the reasons for establishing a formal healthcare compliance program go beyond ensuring that your organization exercises due diligence in seeking to prevent and detect violations of the law by its employees and other agents. Additional reasons include:

- To develop and maintain effective internal controls that promote adherence to applicable federal, state and local laws and the program requirements of federal, state and private health plans
- To detect misconduct or wrongdoing as soon as it occurs so that the problem can be quickly remedied and adverse consequences minimized

- To advance the prevention of fraud, abuse and waste in providing healthcare
- To disseminate a positive, law-abiding corporate value, creating an atmosphere that discourages wrongdoing

Key Laws

It is important to identify some of the key laws governing compliance as a first step toward educating staff personnel and developing the foundation for the program:

- False Claims Act
- Anti-Kickback Statute
- Self-Referral Prohibitions
- HIPAA
- Examination and Treatment for Emergency Medical Conditions and Women in Labor Statute

False Claims Act. Congress enacted the False Claims Act in 1863, originally to prevent fraudulent practices by defense contractors. The False Claims Act allows private individuals to bring action against parties who have defrauded the government, with a potential reward of half of the amount recovered by the government if the suit is successful.

The False Claims Act has been enforced against healthcare providers who "knowingly" billed the government's Medicaid and Medicare programs for services that were not provided, unnecessary or misrepresented in order to receive higher payment. A broad definition of "knowingly" prevents offenders from claiming ignorance about the false claims when they should have known about them because of their position in the organization.

Of particular note is the ability of private individuals to initiate False Claims actions. Plaintiffs who bring action on the government's behalf are known as *qui tam* plaintiffs; they must be an "original source" alleging the violation, i.e., have direct and independent knowledge of it. A potential *qui tam* plaintiff could be almost anyone a provider interacts with, including employees, consumers receiving care, compliance office staff and competitors. The False Claims Act protects employees who initiate claims, testify about violations or otherwise assist in investigations from retribution for doing so.

Anti-Kickback Statute. The AntiKickback Statute prohibits the offer, solicitation, payment or receipt of remuneration, in cash or in kind, in return for or to induce the referral of a patient for any service that might be paid for by federal health programs or federally supported state healthcare programs. Also prohibited is remuneration for purchasing, ordering or leasing of goods or services (or arranging to do so) that will be paid for by these federal or federally supported healthcare programs. The statute provides for a number of exceptions, known as "safe harbors," which are not considered potential areas of violation, and these are defined in the statute. An attorney specializing in healthcare fraud would be familiar with these.

Seff-Referral Prohibitions. In 1989, Congress passed the Anti-Self-Referral Statute, often known as Stark I after its chief proponent, Congressman Fortney (Pete) Stark (D-Calif.). It

prohibits physicians from referring patients to clinical laboratories in which they have financial interest. The statute was broadened under the Omnibus Budget Reconciliation Act of 1993 (and dubbed Stark II). This expanded the prohibition to a wide variety of healthcare services and prohibited referrals to entities in which the physician or an immediate family member has a financial interest and that will seek payment from a federal health program.

HIPAA . As mentioned earlier, the key provisions of HIPAA relating to healthcare compliance include the broadening of the definition of "knowing and willful conduct" to include acts of "deliberate ignorance" by providers with respect to information and regulation. For example a provider could be accused of "deliberate ignorance" if it does not thoroughly know and apply the up-to-date billing coding rules for submitting claims for payment. HIPAA requires the OIG to establish programs to detect fraud and abuse and encourage the public to report it. The law also requires the mandatory exclusion from Medicare and Medicaid of providers who violate fraud and abuse provisions.

Examination and Treatment for Emergency Medical Conditions and Women in Labor Statute. This statute was passed by Congress to prevent the practice of "patient dumpmg," i.e., providers refusing to treat patients who are uninsured or underinsured. It requires hospital emergency rooms to provide an appropriate screening examination for any individual, regardless of whether he/she is a federal health program beneficiary. Generally speaking, if there is an emergency medical condition or the patient is in active labor, the hospital is required to provide treatment to stabilize the patient prior to transferring him/her to another medical facility.

The Components of a Compliance Program

When developing a compliance program to address these legal requirements, it is important to model it after the seven components that have been set forth by the OIG; it should provide for:

- Written standards of conduct
- A compliance officer and committee
- Effective education and training
- Audits and other evaluation techniques
- Internal reporting processes
- Disciplinary mechanisms
- Investigation and remediation

Written standards of conduct. The first component of an effective compliance program is the development of an employee code of ethics that lists activities employees may and may not engage in while employed by your organization.

All of your employees should be required to accept and agree to the code of ethics as a condition of employment. They should also receive a copy of your organization's compliance program manual. New employees should acknowledge the requirement to report violations of the compliance program and code of ethics, the procedures for doing so and the consequences for failing to report such violations. The hiring process should include certification that the employee has not been excluded from participation in any federal or

state healthcare program or been criminally convicted of any crime regarding the federal or state healthcare programs or any offense involving financial issues.

A compliance officer and committee. The compliance officer is responsible for implementing the compliance program and achieving its goals. Selection of this staff member should be based on his/her record of achievement, high level of integrity, educational accomplishments and familiarity with applicable federal and state law and reimbursement issues.

Your organization should also establish a compliance oversight committee to assist the compliance officer. Prospective members must be examined for their knowledge of the relevant subject matter and for any record of past criminal or civil misconduct.

Effective education and training. It is important to develop a basic compliance seminar to be offered to all new employees to educate and test them about the basic components of the program, the organization's code of ethics and the procedures for reporting violations. You should also establish annual "refresher" courses to review new laws, as well as training programs on specialty topics, such as procedure coding, billing and records documentation. Attendance at the compliance education seminars should be a condition for continued employment.

Audits and other evaluation techniques. The audit must include, at a minimum:

- A review of the coding, billing and documentation practices of the organization and its employees.
- A review of compensation arrangements with healthcare professionals that might pose antikickback or antireferral violations
- Ethics-related interviews with executive leadership regarding business decisions, operations and management
- A review of reported violations and investigative findings, and of the compliance program itself to better address such violations
- A review of documents and other written material generated by the organization

The audit should also involve network providers, if they exist. Audit reports should be issued that inform both senior management and the board of directors of the strengths and weaknesses the compliance program and how it might be altered to prevent violations in the future. He audit process should be discussed to determine if it should be changed in scope or frequency to better detect violations.

Internal reporting processes. Your organization must ensure that employees can easily report violations or suspected violations of the code of ethics, usually through a widely advertised hotline. No retaliatory action can be taken against any employee who reports a violation, regardless of the seriousness of the violation or the level of employee or agent responsible for it. The reporting employee's anonymity should be preserved to the extent possible. If disclosure of the employee's identity occurs, the compliance officer must ensure that the employee is not disciplined, ostracized or penalized in any way for reporting the violation.

Disciplinary mechanisms. A compliance program cannot be effective unless you develop and enforce a policy that will punish employees if they violate the code of ethics or if they should have known of such violations as part of their job responsibilities. The nature and seriousness of the violation should dictate the level of punishment.

Employees who are convicted of criminal acts relating to patient care or compliance with federal or state law should be terminated immediately. If criminally charged, employees should be relieved of all duties and should not have access to the organization until the matter is resolved.

Investigation and remediation. Violations of the mandates of the program and code of ethics should be investigated and substantiated by the compliance officer in a timely manner. When a credible report of a violation is received, the first step is to protect any relevant information that is needed to perform a thorough investigation. All document disposal practices should be stopped immediately. If reasonable suspicion exists that employees might destroy or remove documents, the employees must be suspended or removed from sensitive areas.

If a violation of civil or criminal, federal or state law is detected, your organization must report the violation to the appropriate government agency as soon as possible. You should provide a report of your internal investigation and cooperate with the government's investigation. If the violation has resulted in an overpayment, you must promptly return the overpayment in compliance with the payer's required procedures.

Getting Started

It's important to start with the basics, i.e.:

- Develop a board resolution endorsing the creation of the compliance program and giving the compliance officer appropriate authority.
- Develop a formal job description for the compliance officer.
- Seek legal counsel as soon as possible for ensuring protection under attorney-client privilege and to advise and review all aspects of the program.
- Establish a compliance committee with requisite qualifications.
- Perform a preliminary compliance assessment of your organization, focusing on billing, medical records, admission and referral mechanisms, and provider credentialing and contracting.
- Develop a preliminary compliance corrective action plan.

Once you've completed these steps, it's simply a matter of developing a work plan and timetable for implementing the seven key components of an effective program and the corrective action plan. Remember that a healthcare compliance program is not merely a written plan and document. It is an ongoing, continually evolving organizational process.

This article by Joe Naughton-Travers originally appeared in the July/August 2001 issue of *Behavioral Health Management.* For more information, go to the *OPEN MINDS* web site at: http://www.openminds.com/bhm.htm.