“Surviving Healthcare Fraud Investigations”

June 21, 2007

By Jacqueline C. Baratian, Esq.
Alston + Bird
202-756-3484 (Office)
202-756-3333 (Fax)
Jacqueline.Baratian@alston.com

Who Is the Government?

- Centers for Medicare and Medicaid Services ("CMS") (formerly HCFA)
- Office of Inspector General
- Federal Bureau of Investigation
- Department of Justice
- United States Attorneys' Offices
- State Attorneys General Offices
- State Medicaid Fraud Control Units

Who Is the Government? (Cont'd)

- Internal Revenue Service
- Federal Trade Commission
- Food and Drug Administration
- U.S. Postal Service
- U.S. Secret Service
- Federal Employee Health Benefits Program
- Managed Care Organizations

Who Is the Government? (Cont'd)

- Intermediaries, Carriers, and DMERCs under Contract with CMS
- Private Insurance Companies
- Private Organizations under Contract with OIG
- Medicare and Medicaid Program Beneficiaries
- Qui Tam Relators, Including Employees, Former Employees, and Competitors

Government Investigative Techniques

- OIG Subpoenas
- Grand Jury Subpoenas
- Search Warrants
- Civil Investigative Demands (31 USC 3733)
- Authorized Investigative Demands (18 USC 3486)
- OIG Demands for Immediate Access
- Interviews

OIG Compliance Guidance

- Clinical Laboratories;
- Hospitals;
- Home health agencies;
- Third-party medical billing companies;
- Durable medical equipment, prosthetics and orthotics suppliers;
- Hospices;
- Medicare+Choice organizations (now referred to as “Medicare Advantage”);
- Nursing facilities;
- Individual and small group physician practices;
- Ambulance suppliers;
- Pharmaceutical manufacturers; and
- Recipients of U.S. Public Health Service research awards.

Why have a Compliance Program?

1. It is a good business practice.
2. With the promulgation of the Federal Sentencing Guidelines in 1991, an increasing number of organizations have developed compliance programs that meet the Guideline requirements.
3. Some organizations have been required as a result of settlements reached with DOJ and OIG. Compliance obligations are customarily set forth in a Corporate Integrity Agreement.
4. Not having a compliance program can seriously comprise the organization's defense when the government alleges a violation has occurred. Compliance programs are designed to mitigate risks in a heavily regulated industry.

Why have a Compliance Program? (cont'd)

5. Benefits inure to the organization, including early detection of potential problems; reduction in sanctions for violations (under the Sentencing Guidelines); and creation of an organizational culture of intolerance of illegal conduct which, in turn, bolsters public confidence in the company's ethics.
6. As part of potential settlement negotiations with DOJ and OIG, an organization with an established, robust and effective compliance program may receive a Certification of Compliance Agreement (CCA) instead of a Corporate Integrity Agreement (CIA). (Open Letter factors in Nov. 20, 2001 letter).

HHS-OIG Compliance Program Guidance

Chapter 9 identifies nine “basic” elements to develop a comprehensive compliance program:

1) Written policies and procedures
2) Compliance Officer
3) Compliance Committee
4) Effective training
5) Effective lines of communication
6) Enforcement standards
7) Auditing and monitoring
8) Prompt response to offenses
9) Voluntary reporting mechanism

*The Sentencing Guidelines provide eight essential elements for a compliance program.

Written Standards of Conduct and Policies and Procedures

Code of Conduct is fundamental because it articulates the organization's commitment to ethical conduct.

Code of Conduct details the fundamental principles, values, and framework for action within the organization.

Policies and procedures should identify and respond to risk areas. Policies and procedures should be tailored to the organization.

Designation of Chief Compliance Officer (CCO) and Other Bodies Charged with Compliance (*e.g.* Compliance Committee)

The CCO is charged with overall responsibility for operating and monitoring the compliance program.

The day-to-day operational responsibilities can be delegated, but ultimate reporting must be to organizational leadership and the Board of Directors. CCO must have direct access to the Board and senior management.

Dual responsibilities of CCOs are suspect to the OIG.

Independence of the CCO is very important to the OIG. CCO shall not be subordinate to the General Counsel or Chief Financial Officer.

CCO must have sufficient personnel and financial resources to implement fully all aspects of the compliance program.

Training and Education Programs

Training is a key element in demonstrating that the organization's compliance program is effective. The absence of a documented training program will nullify the effectiveness of an organization's compliance policies and procedures.

Specific training should take place with respect to identified risk areas. (*e.g.*, marketing practices, claims submission, coding)

Effective Lines of Communication

Establish a Disclosure Program –create a mechanism to enable employees to disclose potential violations and problems.

The OIG encourages the use of hotlines, newsletters, e-mails, suggestion boxes, and other forms of information exchange to maintain open lines of communication.

The Disclosure Program should emphasize non-retaliation, nonretribution, and confidentiality.

Incorporate a “hotline” for employees to anonymously report compliance problems or violations.

Good faith inquiries should be made into matters that suggest substantial violations and should be documented and investigated promptly.

Maintain a disclosure log.

Enforcement of Disciplinary Action

An effective compliance program should have clear and specific disciplinary policies and procedures. Adhere to those policies and procedures.

Intentional and material noncompliance should subject transgressors to sanctions.

Corrective action should be directed to specific instances of misconduct, as well as to systemic defects.

Sanctions may range from oral warnings to suspension to termination.

Internal Monitoring and Audits of Compliance and Corresponding Risk Assessment

The OIG strongly emphasizes internal monitoring and audit functions when assessing a compliance program.

The development of audits and other risk evaluation techniques are essential to monitor compliance, identify problem areas, and assist in the reduction of identified problems.

Resource binders with relevant guidance – (*e.g.*, CMS directives, carrier bulletins, OIG issuances)

Reporting and repayment of identified overpayments are integral.

Conduct exclusion screenings – HHS/OIG List of Excluded Individuals and GSA List

Prompt Voluntary Reporting

- Take corrective action and document such action.
- Based upon credible evidence of misconduct and after a reasonable inquiry that the misconduct may violate criminal, civil, or administrative law should be promptly reported.
- Reporting of such conduct will be considered a mitigating factor by the OIG (*e.g.*, penalties, assessments, and exclusion).
- OIG Self-Disclosure Protocol – one potential avenue to consider

Ongoing Assessment of the Effectiveness of the Compliance Program

- GOAL – Continually foster the development of a corporate culture of compliance. Be proactive.
- Coordination and Communication – *(e.g.*, effectively communicate regulatory changes to include accountability for implementation)
- Training is essential to an effective compliance program.
- Stay current. Ensure that policies and procedures are frequently reviewed.
- Corrective action plans are essential.