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Review of Compliance

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The Dawning of the Age of Compliance

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It certainly comes as no surprise to providers to suggest that today's health care fraud enforcement climate is very different from even a few years ago. The amount of resources dedicated to enforcement activities has grown dramatically each year since 1992. Civil actions and criminal prosecutions initiated by the Department of Justice ("DOJ") have increased sharply. On the civil side, the government's principal tool has been the False Claims Act, under which it can recover triple its damages plus a penalty of between $5,000 and $10,000 for each fraudulent request for reimbursement (1). Federal criminal prosecutors can allege kickback (2), mail fraud (3), making false statements in connection with claims submitted to Medicare or state health programs (4), and conspiracies to defraud the government (5). Moreover, providers have come to dread a new player in the enforcement game: qui tam lawsuits filed by "whistle blowers" on behalf of the government who will ultimately share as much as 30% of any recovery. As a result of this increased enforcement activity, the government has been recovering hundreds of millions of dollars from providers and imposing serious criminal sanctions on wrongdoers.

The government has begun to emphasize the importance of compliance programs. For example, as part of the $324 million National Medical Enterprises civil settlement in 1994, the government imposed a 22-page compliance program upon the company – a practice followed as well in the $160 million Caremark, Inc. settlement in 1995. In fact, by direction of Attorney General Reno, every settlement entered into by DOJ must contain some provisions addressing compliance procedures.

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The Sentencing Guidelines for Organizations (1991) mandate lesser criminal penalties for companies which have "effective" compliance plans in operation (6). For example, under the Sentencing Guidelines, if two entities are guilty of the identical offense, the entity with a compliance program in place will receive a significantly reduced penalty compared with an entity which has no program in place. DOJ's Civil Division over the last several years has implemented a similar approach by treating civil defendants with meaningful compliance programs in a more lenient fashion than those without such plans.

The government's current enforcement philosophy emphasizes preventing violations by health care providers from arising, rather than just recovering monetary damages and penalties and imposing criminal sentences if violations should occur. This is why compliance programs have become so important: their goal is to prevent violations of law or regulations, or if violations do occur, afford a mechanism to rectify the problem and, perhaps, inform the government. Given this consideration, institution of a plan before a provider is investigated is considered a definite plus by the government.

General Enforcement Environment

In the current adverse enforcement environment, a compliance plan is the most effective strategy for a health care provider to implement in order to reduce its risk of being the target of federal investigation and enforcement action. That risk is now greater than it has ever been. While the Office of the Inspector General ("OIG"), Department of Health and Human Services, has always been the key agency involved in health care fraud investigations, other agencies are now joining the effort. For example, since Attorney General Reno designated health care fraud as her number two enforcement priority, DOJ has committed

substantial additional investigative and prosectorial resources to this area (7).

The enhanced enforcement activity is also getting a boost from another source. During the last three years, qui tam, or "whistle blower" suits filed under the False Claims Act (8), have been a principal source of investigation and prosecution. These suits, often filed by disgruntled ex-employees, competitors, customers, or even former federal agents, trigger an investigation by the United States government. If DOJ determines that the allegations have merit, it will assume responsibility for litigating against the defendant under the False Claims Act, and when there is a recovery, the relator (i.e., the individual filing the complaint), is rewarded with 15-25% of the recovery. Even should the government fail to intervene in the case, the relator may prosecute the case on behalf on the United States, and, if successful, will recover as much as 30% of the final award (9). During the past few years there have been several multi-million dollar settlements, and the press attention surrounding these awards has generated a flurry of additional qui tam actions.

Government-Imposed Compliance Programs

Public statements made by the enforcers suggest that stringent compliance programs will be imposed as part of any health care fraud settlement (10). The government will demand that those compliance programs include a number of severe provisions. For example, the compliance plan must have a minimum duration of five years, include authorization to interview employees without counsel present; and involve annual compliance reviews and audits conducted by independent third parties. There must be prompt disclosure of any credible evidence or civil or criminal misconduct by any employee or any person under contract to the disclosing entity. The company will be expected to waive the attorney-client privilege with respect to any complaint or subsequent investigation of a suspected violation. Finally, the compliance program will be fully imposed upon any subsequently acquired facilities or entities.

Even if a compliance plan has not been implemented before a government investigation and subsequent negotiations commence, counsel representing the provider should nonetheless prepare a compliance program draft and present it to the government as a basis for discussions. Taking the initiative during negotiations allows the provider, rather than the government, the opportunity to define the pertinent issues and choose the appropriate corrective devices (11). This consideration is especially important because the government will seek to impose a compliance program that is advantageous to it – and potentially expensive and disruptive to the provider – as part of any settlement.

Overview of a Compliance Program

An effective compliance program consists of:

1. An internal compliance review or "legal audit" of the provider's operations (generally focused in one or more targeted areas, such as billing practices, marketing, contracts, referral patterns, etc.)
2. Identification of practices which are improper, illegal, or potentially abusive
3. Drafting an appropriate code of conduct for management and staff
4. Development and implementation of a training program for relevant staff
5. Periodic audit of the provider's future operations in these targeted areas

Based on the success of this program, the provider may wish to expand the compliance review to other areas as appropriate.

The Compliance Review, or "Legal Audit"

The initial step in developing an effective compliance plan is to undertake a comprehensive compliance review, sometimes referred to as a "legal audit." The purpose of the compliance review is to ascertain whether the provider's current practices and procedures conform with all pertinent legal requirements. Such reviews particularly focus upon detecting any potential violations of the Medicare/Medicaid anti-kickback law, 42 U.S.C. § 1320a-7b(b), the Civil False Claims Act, 31 U.S.C. §§ 3729-33, and pertinent regulations. In that regard a typical review might examine such elements as leases and supplier contracts, particularly those with referral sources; physician contracts and methods for documenting physician performance of contractual obligations; procedure manuals; the integrity and accuracy of the provider's billing methods; document destruction and retention policies; any audits performed internally or by outside entities such as intermediaries and by outside entities such as intermediaries and governmental agencies; cost report preparation; possible "related party" transactions; and internal audit procedures.

If the preliminary review indicates the existence of potential regulatory problems, then those areas would be examined in depth, possibly with the assistance of outside consultants, in order to ascertain if the provider actually is vulnerable and to make recommendations as to how those existing problems can be corrected. Of course, protecting the attorney-client, attorney work product and self-evaluative privileges is a paramount consideration (12). As part of this process, it should be decided whether a written report is necessary or whether an oral briefing will suffice. Some attention should be given to whether the provider is required by law to make disclosure to the government of any irregularities, or if such disclosure tactically would be advisable as a prelude to possible negotiation.

Once any existing problems have been identified and addressed, or in the event that the initial review discloses no troublesome areas, the next step is to fashion a compliance program specifically designed to address the kinds of risks the provider faces in today's unfavorable enforcement climate. Each of the compliance plan's core elements should be developed in conjunction with the provider's management and in-house counsel reflecting the unique aspects of each provider's business activities.

Designing the Provider's Code of Conduct

The first item on the agenda in designing any compliance program is to undertake an examination of the corporate goals and philosophy of the provider. This analysis serves as a necessary prelude to the development of a code of fundamental standards to be followed by management and staff. The government considers the corporate code of ethics as a key element of any compliance effort. This code should emphasize the provider's commitment to compliance and integrity in all of its operations and must be written so that all employees understand its full meaning.

Essentially, the code is a statement of the fundamental values upon which the provider stands, such as its promise to adhere to all pertinent laws and regulations, its dedication to advancing the effectiveness and quality of its services, and its commitment to treat its clients or customers in an honorable and ethical fashion. The government takes very seriously the need for a corporate code of ethics, and believes that any compliance program is deficient without one. Because the code of ethics is the core of the compliance program, it is essential to seek the input of management and employees (13).

The Central Actor – the Compliance Officer

A second major step is to develop procedures to implement the provider's code of ethics. Most providers create the position of "compliance officer" who has the responsibility for implementing the code of ethics. It is important that the compliance officer work independently of the company's operations, finance, and marketing functions. Generally, this individual has the ability to deal directly with the Board of Directors; often the compliance officer is supervised by an Executive Compliance Committee established by the Board. In addition, as part of the implementation program, most larger providers establish a hotline to facilitate anonymous reporting of any suspected improper activity. The compliance officer is responsible for documenting all hotline reports and corrective actions undertaken as a result of those reports. The compliance officer also oversees any internal audits and investigations generated as a result of the hotline reports and the internal investigation discussed above, which is undertaken as part of the initial establishment of the compliance program (14).

It is important that the compliance officer establish procedures through which employees can seek clarification of ethical issues arising under the code or make suggestions about the operational effectiveness of the compliance program. Not only is facilitating employee communications an effective device to assure smooth implementation of the compliance program, but it also serves to discourage employees from filing qui tam lawsuits out of frustration.

The implementation phase also involves the identification of those circumstances where the provider concludes it should notify the government of certain improprieties which have been discovered. Therefore, part of the compliance program is to set up procedures to enable a provider to identify those situations where notification is appropriate, and those where notification is not appropriate.

Employee Training

A third major component is the education of staff about the compliance program, the provider's obligations, and their own individual obligations and responsibilities. This training has a two-fold purpose:

1. Educating the staff about the provider's philosophy and commitment to integrity;
2. Focusing on the substantive "do's and don'ts" in connection with the staff's activities.

A central objective of staff training is to ensure that employees understand they have an explicit obligation to report all violations of the code and any suspected illegal conduct, and they will be disciplined should they violate that obligation. The government expects that staff education should not be a single event, but rather, an ongoing responsibility. In order to demonstrate the effectiveness of this training, it is advisable that providers document the progress of raising the consciousness of their staff through the periodic surveying of the employees and publishing of the results.

Delegation of Discretionary Authority

One of the most important directives in the Sentencing Guidelines relates to delegation of discretionary authority to employees. The company must institute measures designed to foreclose delegation to individuals who the company knows, or should know through the exercise of reasonable diligence, have a "propensity" to engage in illegal activities. At a minimum, this guideline would seem to require some manner of evaluation of employees who exercise discretionary authority to ensure that no indicia of improper propensities are present. The provider should also undertake careful evaluation of prospective employees through appropriate background screening procedures. Consultation with experienced labor relations counsel is essential to ensure that only appropriate procedures are followed.

Certainty of Discipline

Monitoring procedures also should be instituted to ensure that any employee or member of management who acts contrary to the plan's ethical commitment, through violation of the code, pertinent law or regulation, receives immediate discipline. Usually the compliance officer reviews all disciplinary actions taken against any staff member to ascertain if they involve violations of the standards of conduct or the compliance plan and to determine if appropriate discipline has been imposed. The government looks to the certainty, consistency and severity of personnel actions as a vital indicator of the effectiveness of a compliance program. Once again, careful coordination with experienced labor counsel is essential in designing this element of the compliance plan.

Continuing Compliance

Finally, the responsibility under a compliance program is an ongoing one. As new government regulations and policies are promulgated, it is critical that the appropriate individuals in the field receive proper guidance according to prescribed procedures. Thus, it is important to have periodic updates for staff and for the provider to monitor the staff's understanding of the applicable rules. Usually, this obligation falls to the compliance officer as well.

Monitoring Compliance

The compliance officer should institute a plan for periodic internal audits of selected facets of the provider's operations. The areas to be focused on and audited should be those problem areas identified in the original compliance audit. The compliance officer will determine who the audit teams shall comprise based upon consideration of what particular expertise is required. Audit teams can consist of employees, outside accountants, consultants, and counsel depending upon the subject being audited.

A very useful monitoring device is exit interviewing. Usually it will be the responsibility of the compliance officer to make certain that an exit interview is conducted with each employee terminating employment. The purpose of this interview is to solicit information about possible violations of the Code so they may be investigated. A second purpose of the exit interview is to determine whether the departing employee has any suggestions for improving the compliance program, especially if the employee felt particular elements of the program were not working in a satisfactory fashion. Exit interviews can be followed up with subsequent post-employment questionnaires.

A final method through which the provider should monitor its performance is periodic internal audits of the compliance program itself. Those audits should focus on employee training in the compliance program, verify that any reports and inquiries received by the compliance officer have been investigated and resolved; ensure that report-

ing devices are working; guarantee that appropriate discipline has been imposed; and verify that management and staff have been informed of all new pertinent laws and regulations.

A Plan to Respond to Investigations

A comprehensive compliance plan will also address how the provider and its employees should respond to external investigations by law enforcement or regulatory authorities. Many of the advantages of an effective compliance plan can be compromised by an ill-advised or uninformed response to an unanticipated inquiry. A proactive plan, prepared in advance, with clearly-established procedures and defined individual responsibilities, is a logical component to an overall compliance plan. A surprise inspection can often lead to further scrutiny of the organization, and the reaction to such an administrative inquiry can influence the course of the investigation. No matter how honest and law-abiding the company, a confused response to an investigation can never advance the organization's interests (15).

Why Institute a Compliance Program Now?

Given the above considerations, it is highly advantageous for any health care provider to give serious consideration to instituting an effective compliance plan. The increased number of government investigations, coupled with the virtual explosion of qui tam lawsuits against health care companies, makes it more likely that providers will encounter investigations and possible civil and criminal prosecution. An effective compliance plan can prevent violations of the law; it sends the right kind of signal to the government should a company come under enforcement scrutiny; it mitigates any penalties should enforcement action be taken (16); and it limits to an important extent the government imposing its own expensive and disruptive compliance program upon the provider. Most basically, compliance program are not only good investments, they are the ethical thing for the conscientious provider to do.

Endnotes

1. 31 U.S.C. §§ 3729-33.
2. Medicare/Medicaid Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).
3. 18 U.S.C. §§ 1341, 1343, 1345.
4. 42 U.S.C. § 1320a-7b(a).
5. 18 U.S.C. § 286.
6. United State Sentencing Commission Guidelines, Sentencing for Organizations, 56 Fed. Reg. 22762 (May 16, 1991).
7. *See generally, Department of Justice, Health Care Fraud Report, Fiscal* 1994.
8. 31 U.S.C. § 3730.
9. *See* Bucy, *Civil Prosection of Health Care Fraud*, 30 Wake Forest L. Rev. 693, 707-721 (1995).
10. Comments by William Heffron, Esq., OIG, Office of Civil Fraud and Administrative Adjudication, before the Health Law Section of the District of Columbia Bar, May 3, 1995.
11. Preparation of a compliance program draft by the provider also serves as an effective device to deflate any extreme settlement demands asserted by the government because correcting the problems giving rise to the government's concerns is as fundamental to the Attorney General as securing a financial recovery. Moreover, by admitting that corrective action needs to be implemented, the focus of negotiations is upon resolving a problem, not arguing culpability.
12. Conway, Self-Evaluative Privilege and Corporate Compliance Audits, 68 S. Cal. L. Rev. 621 (1995).
13. See generally, Pitt and Groskaufmanis, Minimizing Corporate Civil and Criminal Liability: A Second Look at Corporate Codes of Conduct, 78 Geo. L.J. 1559 (1990).
14. See Webb and Molo, Some Practical Considerations in Developing Effective Compliance Programs: a Framework for Meeting the Requirements *of the Sentencing Guidelines*, 71 Wash. U.L.Q. 377, 388 (1993).