

Arent Fox Alert:
What Is A Healthcare Fraud Compliance Program
And How Can A Provider Design And Implement One?

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I. WHY ARE COMPLIANCE PLANS ESSENTIAL?

A. Introduction

It certainly comes as no surprise to members of radiology practices to suggest that the today's health care fraud enforcement climate is very different from that of 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 kickbacks, ⁽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⁾ just to name a few pertinent criminal statutes. Moreover, providers have come to dread a new player in the enforcement game: qui tam law suits filed by "whistleblowers" on behalf of the government who will ultimately share as much as 30% of any recovery.

At the very same time that the government has been recovering hundreds of millions of dollars from providers and imposing serious criminal sanctions on wrongdoers, it also 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. The Office of Inspector General at the Department of Health and Human Services has begun promulgating model compliance plans for providers, including hospitals and laboratories.

The **Sentencing Guidelines for Organizations** (1991) mandate lesser criminal penalties for companies which have "effective" compliance plans in operation. ⁽⁶⁾ In other words, under the Sentencing Guidelines, if two entities are guilty of the identical offense, the entity with a compliance program in place will receive a 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 preventing violations of law or regulations, or if violations do occur, affording 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.

B. Whistleblowers' Join an Adverse 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 a 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 prosecutorial 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 "whistleblower" 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 a mandatory 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 of 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 hundred million dollar settlements, and the press attention surrounding these awards has generated a flurry of additional qui tam actions. DOJ estimates that the number of health care qui tams filed will double each year; 400 or so such suits are expected to be filed this year alone.

C. Threat of 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 of 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 must be fully imposed upon any subsequently acquired facilities.

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 to define the pertinent issues and choose the appropriate corrective devices instead of the government. ⁽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.

II. WHAT ARE THE ELEMENTS OF A COMPLIANCE PROGRAM?

Usually, a 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) appointment of a compliance officer and compliance oversight committee; (5) implementation of a hot line or some other manner of reporting mechanism; (6) development and implementation of a training program for relevant staff; (7) design of appropriate disciplinary sanctions for violations of the plan; (8) securing continuing compliance through proper dissemination of new regulations, carrier or intermediary directives and statutes; and (9) periodic audits of the provider's practices and procedures to ensure continued compliance. Based on the success of this program, the provider may wish to expand the compliance review to other areas as appropriate, such as OSHA or FDA compliance.

III. HOW DOES A PRACTICE GET STARTED?

A. The Compliance Review or "Legal Audit"

The foundation for a truly "effective" compliance plan is developed before the compliance program itself is designed and implemented. A rigorous "legal audit" or compliance review accomplishes this objective. The legal audit is nothing more than a comprehensive internal investigation of the provider's operations, generally focused on one or more targeted areas. 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 Federal Health Care Anti-kickback law, 42 U.S.C. § 1320a-7b(b), the civil False Claims Act, 31 U.S.C. §§ 3729-33, and pertinent regulations.

The investigative techniques employed in a legal audit include reviewing pertinent documents and interviewing key individuals who are either identified in the document review or hold essential positions (the director of billing operations, for example). Each type of health care provider has certain unique facets of its operation that should be examined (e.g., compliance with the new teaching physician rules in teaching hospitals); other issues should be examined for all providers (billing practices are a good example). 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/carriers and governmental agencies; cost report preparation; possible "related party" transactions; and internal audit procedures.

Once the compliance review is completed, its diagnostic findings can serve multiple purposes. 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⁾ Before the compliance plan is instituted, any problems should be corrected and any necessary procedures implemented to foreclose their reoccurrence.

As regards designing the compliance program, the review's results should highlight any existing problems so that special attention can be devoted in the Standards of Conduct to preventing a reoccurrence. Addressing particular problem areas in the Standards also demonstrates to the government that the compliance plan is not an "off-the-shelf" document but a program custom designed for that particular provider. The compliance officer as well should be informed of the audit's results so that she may devote special attention to these potential problem areas. As part of this process it should be decided whether a written report is necessary or if an oral briefing or an "exit report" on the preliminary

findings will suffice. Again, protecting privilege can be a paramount consideration at this stage.

It is also important that a determination be made, usually in conjunction with counsel, as to whether any existing problems require disclosure to the government and possible negotiation of a resolution. This frequently is a very difficult decision for the provider, who may feel that correction of a problem is sufficient action, especially given today's adverse enforcement environment which often seems to punish providers who are trying to act responsibly. On occasion, counsel may recommend some manner of disclosure, not necessarily under the Inspector General's "voluntary disclosure" program, in order that all regulatory problems (and potential sanctions) are eliminated before the compliance plan begins operation.

The ideal situation is to have identified and corrected all regulatory problems prior to implementation of the compliance plan. Such action demonstrates to the government that the compliance plan is a serious undertaking and that the health care provider is prepared to swallow bitter medicine if necessary in order to cleanse its operations of any problems. Such action can lend an important element of credibility to the compliance plan. In addition, given the extraordinary importance of "whistleblower" or qui tam lawsuits under the False Claims Act (31 U.S.C. § 3730), correcting any problems which the legal audit uncovers can foreclose substantial expense and potential legal and administrative sanctions should a potential whistleblower become aware of them. Many whistleblower suits grow out of employee frustration resulting from management's failure to investigate reports of inappropriate conduct. An effective compliance plan should foreclose this eventuality; it also takes away the moral high ground from whistleblowers who seek to justify their action by claiming that due to management turning a deaf ear to their concerns, "they had no choice" but to file a qui tam complaint.

For any number of reasons, then, instituting a thorough legal audit as a preliminary step to the design and implementation of a compliance plan can be essential to successfully designing and implementing the kind of compliance program the Sentencing Guidelines and the government expect and demand.

B. 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 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. ⁽¹³⁾ 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. ⁽¹⁴⁾

There is no set format for standards of conduct; each practice should adopt a design with which it is comfortable. Several different representative formats are attached as Exhibit A.

C. The Central Actor--the Compliance Officer

A second major step is to develop procedures to implement the provider's code of ethics. The practice

should create the position of "compliance officer" who has the responsibility for implementing the code of ethics. 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. In addition, as part of the implementation program, most larger providers establish a hotline to facilitate the 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. ⁽¹⁵⁾

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 -- as mentioned above -- 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.

D. The "Interim" Compliance Plan

It is not necessary to wait until drafting is completed on the compliance plan to put an "interim" plan into operation. An interim plan requires: (a) interim standards of conduct; (b) an interim compliance officer be in place; (c) initial employee compliance training taking place; and (d) an interim reporting system exists for making reports of suspected violations of the standards of conduct to the compliance officer. One advantage of interim plans is that they can "get up and running" almost immediately once an interim or permanent compliance officer is designated. However, interim plans are just that -- temporary devices that should be replaced with a complete compliance plan as soon as feasible.

E. Drafting the Compliance Plan

The practice should prepare a written compliance plan which addresses all elements mandated by the Sentencing Guidelines. It is usually advisable to first select a compliance officer before drafting the plan so that the compliance officer can help design the compliance procedures for which he or she will be responsible for implementing. While counsel can participate in drafting the plan, members of the practice should play a major role because the compliance plan is the practice's pledge to the government and should be carefully crafted to accurately reflect the needs of its members. The practice should design its own plan; prepared plans or plans copied from those of other practices should be avoided because the government will consider such "shortcuts" to reflect adversely on the commitment of the practice to implement a truly "effective" compliance plan.

There is no set blueprint for a compliance plan; each practice should develop whatever particular format meets its needs and with which it is comfortable. A brief generic model plan is attached for reference as Exhibit B. Whatever format the practice chooses, a typical compliance plan should contain the following elements:

A. Introductory explanatory letter to employees.

B. Explanation of how the compliance plan operates, including how violations are reported and employee obligations.

C. The Standards of Conduct.

D. The Role and responsibilities of the compliance officer and the compliance oversight committee (if the practice decides to have one).

E. Investigative protocol.

F. An audit protocol.

G. Discussion of compliance training.

H. How new statutes and regulations will be implemented.

I. Exit interviews

J. Annual review and report on how effectively the compliance plan is functioning.

K. Role of discipline and how reviewed.

L. Exercising due diligence in selecting employees.

M. Periodic evaluation of the compliance officer.

F. Employee Training

One extremely important component of any effective compliance program is the training of staff and practice members about the compliance program, the practice's obligations, and their own individual obligations and responsibilities. This training has a two-fold purpose: (1) educating the staff and physicians about the practice's philosophy and commitment to integrity; and (2) focusing on the substantive "do's and don'ts" in connection with the staff and physician practices and procedures. A central objective of compliance training is to insure that employees and physicians alike 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 compliance 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 the practice document the progress of raising the consciousness of its staff and physicians through periodic surveying, including publishing the results.

G. Monitoring Compliance

The compliance officer should institute a plan for periodic internal audits of selected facets of the practice's operations. The areas that will be audited should particularly focus upon any problems areas identified in the original compliance audit. In addition, the compliance officer must be prepared promptly to investigate any "hotline" reports of suspected inappropriate conduct. The compliance officer will determine who shall comprise the audit teams 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 conduct an exit interview 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 will monitor its performance is through periodic internal audits of the compliance program itself. Those audits should focus on employee training in the code and the compliance program; verify that any reports and inquiries received by the compliance officer have been investigated and resolved; insure that reporting 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.

H. Delegation of Discretionary Authority

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

I. Certainty of Discipline

Monitoring procedures also should be instituted to insure that any employee, physician or member of management who acts contrary to the plan's ethical commitment, through violation of the code, pertinent law or regulation, would receive immediate discipline. Usually the compliance officer reviews all disciplinary actions 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.

J. Continuing Compliance

Finally, the responsibilities the practice assumes under a compliance program are ongoing ones. 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.

K. Final Thoughts

While designing a compliance plan can appear intimidating, it is important to remember that each practice has a great deal of discretion in designing its own plan. The government only expects a practice

to undertake a compliance plan that is feasible for its particular circumstances. Your practice is not required to have a 50-page National Medical Enterprises plan; only one that is appropriate for its size and resources. The only option that your practice does not have given the current enforcement environment is to do nothing about compliance and hope that problems never emerge. A miscalculation in this regard could prove fatal both to the practice and to its individual members who share potential liability under the False Claims Act, the Federal Health Care Anti-kickback law, and various other criminal and civil statutes.

EXHIBIT A

[VERSION A]

BILLING STANDARDS OF CONDUCT

Compliance with Applicable Laws and Regulations Regarding the

Billing of Services to Governmental Health Plans

Basic Pledge:

While providing superior health care is a primary goal of _____, complying with applicable federal and state laws and regulations regarding billing is equally important. To the extent within its control, _____ pledges to conform its billing process with all pertinent federal and state laws and regulations. We will also strive to ensure, to the extent reasonably feasible, that all physicians, staff, suppliers and contractors act in conformity with this compliance plan and all pertinent federal and state laws and regulations pertaining to the billing of public insurers.

Standards of Conduct:

1. All treatment recommended and implemented at _____ will be medically necessary; medical necessity is determined by the accepted professional standards of the relevant medical profession. Treatment decisions will not be affected by the type of insurance the patient has or whether a patient is able to pay co-payments or deductibles.
2. _____ will not pay any person or entity any form of remuneration for the referral of patients. Such "kickbacks" are not only illegal but are also unethical and will not be tolerated.
3. It is also illegal and in total contradiction of _____'s policy to offer any financial inducement, gift or bribe to prospective patients in order to encourage them to undergo treatment at _____.
4. All billing and patient records will be accurate, complete and as detailed as required by government and professional standards. Each step in the treatment process, from admission through discharge, shall be documented appropriately in the patients' medical records.
5. In order to ensure accurate billing, _____ will implement a system which allows billing personnel to verify charges against the services documented in the patient records. If any person has a question about whether an entry in a patient record or billing document is appropriate, that employee should discuss the matter with a supervisor or the compliance Officer.

6. With respect to physicians who involve residents in their patients' care, Medicare Part B (physician fee schedule) payment will be sought for the teaching physicians' services provided to patients only if the teaching physicians (i) personally furnish the services, (ii) furnish the services jointly with the resident or (iii) are present with the resident for the key portion(s) of the service(s) when the resident furnishes the services.
7. The documentation for teaching physician services will adhere to the rules established by HCFA at § 15016 of the Carrier Manual entitled "Supervising Physicians in Teaching Settings" (distributed on May 30, 1996). Appendices A & B to this compliance plan are incorporated herein by reference and should be reviewed.
8. Periodically, during the course of the patient's stay, the medical record shall be reviewed by the attending physician to ensure that all appropriate documentation has been created and properly filed.
9. All requests for reimbursement submitted to federally-funded insurance programs (e.g. Medicare, Medicaid, or CHAMPUS), will contain only true and accurate data. Furthermore, no service will be billed unless fully justified by the instructions of the medical staff as reflected in patient records.
10. All reports required by state or federal law shall be filed on time and contain only information that is true and accurate.
11. Any proposed referral by a physician to a _____ facility, when that physician has an ownership or other financial interest in such _____ facility, shall be reviewed prior to the billing for services for conformity with both federal and state self-referral laws.
12. All work performed and services rendered by Medical Directors and other part-time employees shall be documented fully in appropriate records.
13. _____ will be forthright and candid in dealing with any governmental billing inquiries. Any requests for information will be responded to with complete, factual, and accurate information tendered with a cooperative attitude.
14. Any decision to grant a waiver of co-payments or deductibles will be made in accordance with written guidelines developed by _____ which employ appropriate standards for determining indigence. Any waiver decision should be based exclusively on financial data provided by the patient, and it should be available only for patients at or below 150% of federal poverty guidelines. All waiver decisions will be fully documented and appropriately placed in each patient's record.
15. _____ will provide employees with all information and instruction necessary to comply with pertinent federal and state laws and regulations related to billing. _____ will also furnish appropriate internal and external training to employees involved in billing activities, as it deems necessary, in order to keep them abreast of new laws, policies and regulations.
16. To the extent feasible, for any managed units, _____ will ensure that all pertinent provisions of this Code of Standards will be implemented fully and to the same extent as for patients admitted to _____-operated facilities.
17. To the extent feasible, _____ will ensure that all pertinent provisions of these Standards of Conduct will bind any independent contractors, temporary employees, or contract employees.

18. It is the obligation of all persons employed or under contract with _____ to respect and protect property; _____ property includes billing and medical records, whether on paper or in the _____ System. No _____ property should be used for personal purposes or misused or misrepresented in any manner. No _____ property should be removed without appropriate authorization.

19. _____ will ensure that no balance billing occurs for covered services rendered to _____ patients as required under federal and state law.

20. _____ will comply with the federal and state laws and regulations governing credit balance reporting and overpayments.

21. _____ cost reports shall be accurate, complete, and fully in conformity with all federal and state requirements. All cost reports shall be supported by appropriate documentation. If any question arises as to the propriety of cost report entries, it should be referred to _____'s counsel and accountants.

[VERSION B]

STANDARDS OF CONDUCT

Standard No. 1: Patient Care, Comfort and Convenience

The primary purpose of _____, and its reason for being, is to provide the finest quality of psychiatric treatment for our patients. We recognize that our practice is patient-oriented, and we welcome it. _____ pledges not only to furnish the highest quality of care possible, but also to make treatment as accessible and convenient as possible for our patients. Our goal is to create a truly caring environment.

Standards of Conduct

1. _____ reason for being is to provide the highest quality of care possible for patients requiring a variety of psychiatric treatments. In discharging that responsibility, the safety and well-being of each patient must be the paramount considerations.

2. We deal with each patient on an individual basis. We will insure that while at _____, each patient's dignity will be respected. We also pledge to insure that every patient understands the reasons for the recommended treatment, how it will be accomplished, if follow-up consultations will be required, and what role medications will play. We welcome the participation of family members in assisting the patient during consultation and treatment.

3. We will furnish each patient with the same level of highest quality care and cost-effective treatment. Treatment decisions are not affected by the patient's payor or financial class. A copy of the treatment plan, with a copy of the discharge disposition, will be given to the patient.

4. All physicians and staff employees of _____ will be licensed, credentialed or skilled at the services they perform.

5. _____ will comply fully with all state and federal laws and regulations regarding patient rights and the confidentiality of patient medical records.

6. On a periodic basis, _____ will review and evaluate its procedures, medical standards, and treatment results to insure that our care remains of the highest quality.

7. We will insure that each patient or their guardian advocate has signed an informed consent before admission for treatment.

Standard No. 2: Compliance with Laws and Regulations

While providing the highest quality of psychiatric treatment as possible is our primary goal, it is not the only responsibility _____ assumes. _____ pledges to furnish treatment in accordance with all pertinent federal and state laws and regulations. We will strive to insure that all physicians, staff, suppliers and operators of managed units act in conformity with all pertinent laws and regulations.

Standards of Conduct

1. All treatment recommended and implemented at _____ will be medically necessary as judged by professional standards of the medical profession. Treatment protocols will not be affected by a patient's payor or financial class.

2. All in-patients shall be reviewed on a daily basis to insure that they meet the criteria for continuing stay based on their diagnosis.

3. _____ will not pay any person or any entity any form of remuneration for referral of patients. Such "kickbacks" are illegal under both federal and state law and will not be tolerated.

4. It is also illegal, contrary to the Medicare fraud and abuse statutes, and in total contradiction of hospital policy to offer any financial inducement, gift or bribe to prospective patients in order to encourage them to undergo treatment at .

5. _____ will not pay for any airline transportation for _____ patients or relatives of patients.

6. All costs related to relatives visiting patients, including travel and lodging, will be borne by the visitors -- not _____.

7. As a service to its patients and the community, _____ will provide free van or other transportation only to patients within a 60-mile radius of the hospital, as well as to and from airports.

8. All billing and patient records will be in compliance with pertinent government and professional standards. Each step in the treatment process, from admission through discharge, shall be fully documented in appropriate medical records. Periodically, during the course of the patient's stay, the medical file shall be reviewed by the continuing care or case management specialist to insure that all appropriate documentation has been created and properly filed.

9. All requests for reimbursement submitted to federally- funded insurance programs (e.g., Medicare, Medicaid, or CHAMPUS) as well as any private insurance provider will not be billed unless the service has been performed and documented in the medical record.

10. Under no circumstances will the _____ treat in-patients solely for chemical dependency. However, it is appropriate to treat "dual diagnosis" patients, i.e., those patients whose primary diagnosis is psychiatric in nature. No dual diagnosis in-patient shall be admitted to _____ without an appropriate written diagnosis by a physician who has reviewed the proposed admission.

_____ will be able to treat patients with chemical dependency issues on an ambulatory basis.

11. All reports required by state or federal law shall be filed _____ on time and contain only information supported by the books and records of the facility.

12. Any contractual or financial relationship with a physician shall be reviewed for conformity with both federal law (Stark laws) and state law.

13. Any contract that can be the subject of federal or state fraud and abuse laws and regulations will be reviewed by _____ counsel for conformity with pertinent state and federal laws and regulations.

14. All work performed and services rendered by Medical Directors and other independent contractors and employees shall be documented fully in appropriate records.

15. _____ shall not pay for any form of aftercare rendered to former patients by other providers.

16. _____ will be forthright and candid in dealing with any governmental inquiries. Any requests for information will be responded to with complete, factual, and accurate information tendered with a cooperative attitude.

17. Any decision to grant a waiver of co-payments or deductibles will be made in accordance with written guidelines developed by the hospital. Any waiver decision based on indigence should be based exclusively on financial data provided by the patient. All waiver decisions will be fully documented and appropriate documentation placed in each patient's file.

18. The hospital will provide employees with all information and instruction necessary to comply with pertinent federal and state laws and regulations. The hospital will also furnish to employees involved in billing activities with appropriate internal and external training, as it deems necessary, in order to keep them abreast of new laws, policies and regulations.

19. Should _____ re-institute managed units, it will insure that all pertinent provisions of this Code of Standards will be implemented fully and to the same extent as for patients admitted to remainder of the hospital.

20. All payments made by _____ to any person or entity

shall be in conformity with contractual obligations or to discharge obligations for supplies, materials and services represented by a written request for payment. Under no circumstances shall payments exceed the amounts specified in the contracts giving rise to the obligation unless written approval is obtained from the hospital Administrator.

21. To the extent feasible and appropriate, the hospital will insure that all pertinent provisions of these Standards of Conduct will bind any contractors, temporary employees, or contract employees.

Standard No. 3: Business Conduct and Practices

In order to satisfy the laws and regulations within which _____ operates, it is essential that our daily business practices maintain the highest standards.

Standards of Conduct

1. All business records must reflect the underlying transactions. All employees must record and report information as accurately and honestly as possible. All patient records, whether medical or for billing purposes, should reflect the services performed. No entry to any hospital record should hide or disguise any fact. If any employee has a question about whether an entry to a patient or billing document is appropriate, that employee should discuss the matter with a billing supervisor or the hospital Administrator.
2. All documents and records should be maintained in accordance with the procedures contained in a written record retention program. No documents or records should be destroyed unless destruction is directed in the hospital's document destruction guidelines. No documents or records should be retained for a period longer than that specified in the guidelines. Copies of the guidelines for document retention and destruction shall be made available by the hospital Administrator.
3. Because _____ is a psychiatric hospital, all hospital records and documents are of a highly confidential nature. Hospital records shall only be disclosed pursuant to the policies established by the hospital. Patient records and documents are particularly sensitive and should always be treated with the highest level of confidentiality. This obligation continues even should an employee terminate employment with _____.
4. It is the obligation of hospital employees to respect and protect hospital property. No hospital property should be used for personal purposes. No hospital property should be removed from _____ without the permission of the hospital Administrator.
5. The hospital's cost reports shall be in compliance with all federal and state requirements. All cost reports shall be supported by appropriate documentation. If any question arises as to the propriety of cost report entries, the hospital's counsel and outside accountants shall resolve the issue.

Standard No. 4: Conflicts of Interest

Hospital employees may not participate in any activities or business endeavors which could pose a conflict with their responsibilities to the hospital. Whenever personal interests or activities of the employee may affect the employee's ability to act in the best interest of the hospital and its patients, then a conflict of interest situation has arisen. Employees should avoid even the appearance of a conflict of interest.

Standards of Conduct

1. Loyalty to the hospital and its mission is a fundamental principle of employment and an employee must constantly review his or her conduct to make sure that not even the appearance of a conflict exists.
2. All decisions made by the employee should be in the best interests of the hospital and its patients -- no considerations can be allowed to undermine this fundamental employee commitment.

3. Employees should avoid placing business, or recommending that business be placed, with a company in which their families or close personal friends have an interest.
4. Employees should not recommend the hiring of close family members without informing the hospital Administrator of that relationship.
5. Except for the occasional modest expressions of gratitude from patients, employees should refuse gifts, loans or anything of value offered by outside individuals or companies if accepting such gifts might make the employee believe he or she has an obligation to the giver of the gift or loan. Receipt of any gift or loan from an outside source should be approved by the hospital Administrator. Under no circumstances should gifts or loans be accepted from outside individuals or organizations that currently conduct business with the hospital or which wish to conduct business with the hospital.
6. With the exception of limited partners, employees must not own, directly or indirectly, an interest in any business which competes with _____, unless the hospital Administrator has given written approval.
7. No outside employment should be permitted if it will interfere or conflict with employment at the hospital. For example, no mention of the employee's association with the hospital can be made in connection with securing or conducting a second job or undertaking self-employment. In addition, employees may not use hospital time, assets, facilities, materials, influence or services for their own outside activities, including charitable work, unless approved by the hospital Administrator.

EXHIBIT B

COMPLIANCE PROGRAM FOR PHYSICIAN PRACTICES

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A Model Compliance Program.

The attached document is a Model Compliance Program for physician practices. As stated previously, each compliance program must reflect the individual practice's philosophy and needs; there is no single program which can be developed and adopted by all practices. Further, a compliance program is not a collection of paper -- it is a dynamic process to which all individuals in the practice must be committed. As a result, the attached Model Program sets forth only the structure for the documents so that each practice will be able to develop and implement its own program. To assist practices in its development, examples of the type of information which may be included are provided. It is up to each practice, however, to develop its own program.

MODEL COMPLIANCE PROGRAM

FOR PHYSICIAN PRACTICES

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TABLE OF CONTENTS

- [Letter to Practice Employees](#)
 - [Description of Ethics Process](#)
 - [Standards of Conduct](#)
 - [Standard 1: Patient Care, Comfort, Convenience, and Respect](#)
 - [Standard 2: Compliance with Laws and Regulations](#)
 - [Standard 3: Business Conduct and Practices](#)
 - [Standard 4: Conflicts of Interest](#)
 - [Compliance Officer/Compliance Committee](#)
 - [Employee Disciplinary Protocol](#)
 - [Appendix A: Plan to Respond to Investigations](#)
 - [Appendix B: Document Retention Policy](#)
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PHYSICIAN PRACTICE

[address]

Addressee

Re: Institution of a Compliance Program

Dear Employee/Colleague:

[This letter should be a simple one page notice advising all employees and individuals in the Practice that the Practice is committed to assuring the provision of quality services to its patients and that it is committed to maintaining compliance with all applicable rules and regulations. The letter may include statements about the need to enlist the assistance of all employees and individuals in the Practice and that it is the responsibility of everyone in the practice to be committed to work toward that common goal. The letter also should explain about the institution of a compliance program and make it clear that all individuals in the Practice are responsible to become familiar with the applicable standards of conduct and to understand their role in the Practice.]

PRACTICE'S ETHICS PROCESS

[Introductory language which sets forth each employee's responsibilities, such as:]

Each employee must recognize that as representative of the [name of practice] he or she has the responsibility to conform with two fundamental tenets of the Practice's compliance program:

- a. Complying with the Practice's standards of conduct; and
- b. Reporting violations of the standards of conduct.

Each is described in more detail below.

A. Complying with the Standards of Conduct.

[This brief section should advise employees that it is their responsibility to conform to the Practice's standards of conduct, encourage them to raise questions about activities which they feel may be

inappropriate, and introduce employees to the Compliance Officer position and the role of the Compliance Officer.]

B. Reporting violations of the standards of conduct.

[This brief statement should impress upon each employee that it is their responsibility to report violations and explain briefly the mechanisms available for such reporting. It should assure employees that, if they wish, the report they file may be done anonymously and that no retribution will result from fulfilling their compliance responsibilities.]

* * *

[The Practice may wish to reiterate the obligation of all employees to follow the standards of conduct, and advise that any violations will be subject to discipline. Finally, employees should be advised that the standards of conduct do not constitute an employment contract.]

STANDARDS OF CONDUCT

[The standards of conduct should reflect the Practice's philosophy and culture, its commitment to general compliance issues, as well as recognition of specific areas on which it must focus. The Practice may wish to solicit suggestions from all employees, although the principals of the Practice ultimately will be responsible for its implementation. Input also should be obtained from the base line audit reflecting legal and billing compliance. Some practices may wish to set forth the standards of conduct under a single heading, while others may wish to divide them into broader categories. This model reflects division into broader categories of conduct, as set forth below:]

Standard No. 1: Patient Care, Comfort, Convenience, and Respect.

[The standards of conduct in this category should reflect the philosophy of the Practice with respect to its patients. The standards should reflect general statements which likely will be consistent with the philosophy of all practices, as well as specific statements reflecting the needs and operations of the individual Practice.]

[The following are examples of a general nature:]

1. The Practice is committed to providing quality care for all patients with medical conditions affecting their eyes. In discharging our responsibility, the safety and well-being of each patient must be the paramount consideration.
2. The Practice will provide each patient with the appropriate level of treatment, regardless of the payment source or level of reimbursement the Practice receives.

[The following are examples of a more specific nature:]

3. Collection of co-payment and deductible from patients will take place only after the primary insurer has paid the Practice.

or

3. Co-payments and deductibles will be collected from patients at the time of their visit. If, however, it is

determined that an improper amount was collected, any credit balance will be refunded to the patient within sixty days of receipt of payment from the primary payor.

[For practices which co-manage:]

4. Any surgery patient who wishes to remain with the Practice for the provision of post-operative care may do so, irrespective of the expectations of the primary vision care physician who referred the patient to the Practice.

Standard No. 2: Compliance with Laws and Regulations

[There should be a brief statement about commitment to comply with all applicable federal and state laws. Following that statement, the relevant standards of conduct, both general and specific, should be enumerated. Examples are as follows:]

[Of a general nature]

1. All treatment recommended and provided at the Practice will be medically necessary and consistent with professional standards of care.
2. The Practice will not pay anyone or any entity for the referral of patients to the Practice.

[Of a more specific nature]

3. The Practice will provide reasonable transportation to patients who require it, but will not advertise the availability of such transportation, as an inducement to patients. Such transportation will be provided in conformance with applicable federal guidelines, to the extent that such guideline are developed.

[Specific items should be listed which reflect problems identified in the legal and/or billing audit as enumerated standards, such as:]

4. Only physicians may determine the applicable ICD-9 code to support the procedure performed.
5. Services provided by physician assistants will be billed with the appropriate modifier.
6. Services will be billed as "incident to" services only when the physician has provided direct supervision of the support personnel.

Standard No. 3: Business Conduct and Practices.

[The standards address issues about maintenance of confidentiality of the Practice's business records, document retention and destruction guidelines, relationships with vendors, and protection of property. Examples include:]

1. All documents will be maintained in accordance with the Practice's records retention program. No documents will be destroyed unless destruction is specified in the Practice's policies.
2. Practice employees must respect and protect the Practice's property. No Practice property shall be used for personal purposes without the express authorization of the Practice Administrator.

Standard No. 4: Conflicts of Interest.

[There should be a general statement about sensitivity to conflicts of interest and the responsibility of employees to avoid them. Standards generally include statements about the employee's responsibility to the Practice, anti-nepotism rules, limitations on employee's accepting gifts or other items of value from patients or referral sources, interests or relationships with competitive practices, etc. Examples are:]

1. All decisions made by employees must be in the interest of the Practice and our patients -- no considerations may undermine this fundamental commitment.
2. No outside employment is permitted if it interferes or conflicts with the employee's ability to fulfill his or her responsibilities to the Practice.

[How the practice decides to assure compliance with these standards should be more carefully spelled out in a policies and procedures manual.]

COMPLIANCE OFFICER/COMPLIANCE COMMITTEE

[This section describes the role of the Compliance Officer and/or Compliance Committee and provides a description of the operation of the compliance program itself. The headings which are included are suggestions -- they may be too restrictive or too broad for certain practice's needs. Beneath each heading is a general discussion of the type of information to be included.]

A. Investigative Protocol

[This section provides a discussion of the duties and responsibilities of the Compliance Officer/Committee in connection with receiving reports of alleged improprieties, which may be made on an anonymous basis, and investigating to determine whether, in fact, there has been a violation of the standards of conduct or of applicable rules and regulations. This section discusses the investigative process to be followed by the Compliance Officer and how findings are reported. In addition, this section should state the policy that there will be no retribution for any individual who files a report to the Compliance Officer.

B. Audit Protocol

[This section should discuss the protocol for performing periodic audits relating to certain facets of the Practice's operations, including billing practices as well as any items which may have been identified as potential problems as a result of prior legal audits.]

C. Compliance Training

[This section discusses the provision of training for employees and the mechanism to assure training for new employees as well as periodic updates for all employees. In addition, this section discusses the mechanism to assure that any new developments which affect the Practice are provided to appropriate employees as expeditiously as possible.]

D. Exit Interviews

[This section discusses briefly the responsibility of the Compliance Officer to conduct exit interviews for employees leaving the Practice in order to solicit information about the Practice's compliance with

the standards of conduct.]

E. Review of Disciplinary Actions

[This section discusses the responsibility of the Compliance Officer to assure that any disciplinary actions taken against employees are consistent with the standards of conduct as well as with the disciplinary protocol of the Practice. This section also provides a mechanism for the Compliance Officer to address any problems in connection with disciplinary actions taken.]

F. Employee Screening

[This section discusses the mechanism used by the Practice to assure that current and prospective employees have not been the subject of any prior sanction action by any governmental or other agency, particularly in connection with duties and responsibilities which they may have as part of their employment relationship with the Practice. The level and intensity of the screen may differ depending upon the responsibility of the employee.]

G. Annual Report

[This section discusses the requirement of the Compliance Officer to provide the Practice with an annual report of all activities undertaken during the year, including assurance that the Practice has implemented the compliance program appropriately, and that disciplinary actions have been taken appropriately.]

H. Evaluation

[Finally, there should be a discussion of the mechanism for evaluating the Compliance Officer, including the specific criteria which will be applied in the evaluation process. In addition, there should be a discussion of what action, if any, should be taken if the Compliance Officer is found to have performed inadequately.]

THE PRACTICE'S DISCIPLINARY PROTOCOL

[This section discusses the responsibility of the Compliance Officer to be certain that all employees understand that the compliance program includes imposition of discipline for violations of standards of conduct. This section also discusses the responsibility of supervisors in the Practice in connection with the application of the disciplinary protocol, how it should be applied consistently among all employees, and the process through which such discipline should be imposed. This section should also discuss the specific items which could subject an individual employee to immediate termination.]

APPENDIX A

PLAN TO RESPOND TO INVESTIGATIONS

[While not a requirement of a compliance program, it is helpful to provide guidance to all employees in connection with their rights and obligations if there should be an investigation of the Practice. This appendix discusses the philosophy of the Practice to cooperate with any investigation, and explains the employee's rights and obligations and to respond if the employee receives inquiries from investigators. This section also should direct employees to notify the appropriate individuals at the Practice in case an inquiry is received on behalf of the Practice.]

APPENDIX B

DOCUMENT RETENTION POLICY

[Again, while this section is not a specific requirement of a compliance plan, it is important to provide employees of a Practice with guidelines concerning when records must be retained and when they may be destroyed.]

NOTES:

1. 31 U.S.C. §§ 3729-33.
2. Federal Health Care Anti-kickback Statute, 42 U.S.C. S 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 States 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 Prosecution 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. A very useful handbook on drafting codes of conduct is American Corporate Counsel Association, ESTABLISHING A CODE OF BUSINESS CONDUCT (1992).
14. 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).
15. 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).
