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**PHYSICIAN PRACTICE
COMPLIANCE PROGRAM**

TABLE OF CONTENTS

I. INTRODUCTION

A. BENEFITS OF A COMPLIANCE PROGRAM

B. THE DIFFERENCE BETWEEN "FRAUDULENT" AND "ERRONEOUS" CLAIMS TO FEDERAL HEALTH PROGRAMS

II. COMPLIANCE PROGRAM ELEMENTS - THE SEVEN BASIC COMPONENTS

STEP ONE: AUDITING AND MONITORING

1. Policies and Procedures
2. Claims Submission Audit

STEP TWO: PRACTICE STANDARDS AND PROCEDURES

1. Code of Conduct
2. Policies and Procedures
3. Specific Risk Areas
 - a. Coding and Billing
 - b. Reasonable and Necessary Services
 - c. Documentation
 - i. Medical Record Documentation
 - ii. HCFA 1500 Form
 - d. Kickbacks, Inducements and Self-Referrals
4. Retention of Records

STEP THREE: DESIGNATION OF A COMPLIANCE OFFICER/CONTACT

STEP FOUR: CONDUCTING EFFECTIVE TRAINING AND EDUCATION

1. Compliance Training
2. Coding and Billing Training
3. Format of the Training Program
4. Continuing Education on Compliance Issues

STEP FIVE: RESPONDING TO DETECTED OFFENSES AND DEVELOPING CORRECTIVE ACTION INITIATIVES

STEP SIX: DEVELOPING EFFECTIVE LINES OF COMMUNICATION

1. Hotline and Other Mechanisms for Reporting Violations
2. Protection of Employees

**STEP SEVEN: ENFORCING STANDARDS THROUGH WELL-PUBLICIZED
DISCIPLINARY GUIDELINES**

III. DEPARTING EMPLOYEES - EXIT INTERVIEW

IV. GOVERNMENT INVESTIGATIONS

V. REPORTING INTENTIONAL WRONGDOING

VI. PLAN MODIFICATION

VII. CONCLUSION

APPENDIX A: EXIT INTERVIEW QUESTIONS

**APPENDIX B: RIGHTS AND OBLIGATIONS OF EMPLOYEES IF CONTACTED BY
A GOVERNMENT ATTORNEY OR AGENT**

APPENDIX C: ADDITIONAL RISK AREAS

I. Reasonable and Necessary Services

- A. Local Medical Review Policy
- B. Advanced Beneficiary Notices
- C. Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services
- D. Billing for Non-covered Services as if Covered

II. Physician Relationships with Hospitals

- A. The Physician Role in The Patient Anti-Dumping Statute
- B. Teaching Physicians
- C. Gainsharing Arrangements and Civil Monetary Penalties for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries

III. Physician Billing Practices

- A. Third-Party Billing Services
- B. Billing Practices by Non-Participating Physicians
- C. Professional Courtesy

IV. Other Risk Areas

- A. Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer
- B. Unlawful Advertising

APPENDIX D: CRIMINAL STATUTES

- I. Health Care Fraud (18 U.S.C. 1347)
- II. Theft or Embezzlement in Connection with Health Care (18 U.S.C. 669)
- III. False Statements Relating to Health Care Matters (18 U.S.C. 1035)
- IV. Obstruction of Criminal Investigations of Health Care Offenses (18 U.S.C. 1518)
- V. Mail and Wire Fraud (18 U.S.C. 1341, 1343)
- VI. Criminal Penalties for Acts Involving Federal Health Care Programs (42 U.S.C. 1320a-7b)

APPENDIX E: CIVIL AND ADMINISTRATIVE STATUTES

- I. The False Claims Act (31 U.S.C. 3729-3733)
- II. Civil Monetary Penalties Law (42 U.S.C. 1320a-7a)
- III. Limitations on Certain Physician Referrals ("Stark Laws") (42 U.S.C. 1395nn)
- IV. Exclusion of Certain Individuals and Entities From Participation in Medicare and State Health Care Programs (42 U.S.C. 1320a-7)

APPENDIX F: CARRIER CONTACT INFORMATION

APPENDIX G: INTERNET RESOURCES

GALEN MEDICAL GROUP **COMPLIANCE PROGRAM**

INTRODUCTION

This Physician's Practice Compliance Program ("the Plan") is intended to ensure that Galen Medical Group (Galen) develops and implements internal controls and procedures that promote adherence to all applicable federal, state, and local laws, rules and policies relating to payment for health care services, including but not limited to billing, coding, claims submission, and improper conduct. Other purposes of the Plan are to:

- Further the mission of Galen to provide compassionate and high quality medical care to our patients;
- further accentuate the organizational commitment to accurate submission of all claims to third parties;
- promote the prevention, detection and resolution of instances of conduct which is not in conformance with applicable federal or state laws, rules and regulations; and
- minimize, through early detection and reporting, any potential loss to the government from erroneous claims, as well as reduce Galen's potential exposure to damages and penalties that might result from questionable activities.

The Plan, having been approved by Galen, constitutes official practice policy. The practice partners, employees and subcontracted physicians who fail to comply with the elements of this Plan may face disciplinary actions including reprimand, suspension without pay, termination, or civil and/or criminal charges.

Our practice has always strived to maintain a good faith effort to comply with applicable regulations and laws. In today's dynamic healthcare environment, Galen has determined that it would be best to organize, centralize and formalize procedures and implement required enhancements, as directed by the U.S. Department of Health and Human Services, Office of Inspector General, to existing corporate policies and procedures.

Galen is committed to pro-active management of its billing processes in order to ensure full compliance with Medicare and other government regulations. The policies and procedures referenced in this document are meant to transcend all partners, employees and subcontracted physicians and vendors of our practice. It is the intention of Galen to enforce all policies and procedures, most importantly those which are designed to detect and prevent issues of non-compliance, so that all reasonable steps necessary to facilitate compliance diligence are enacted. Galen's Compliance Officer, Savannah Knuettel, should be contacted when questions concerning

compliance arise or to report potential violations. At any time, communication to the Compliance Officer may occur either by telephone (423-308-0280 ext. 133), electronic mail (**privacy@galenmedical.com**), memorandum, in person, or through Galen's Compliance box located at each site. To the extent possible, all communication to the Director of Compliance will be treated confidentially.

A. Benefits of a Compliance Program

Galen can gain numerous benefits by implementing an effective compliance program. These benefits may include:

- the development of effective internal procedures to ensure compliance with regulations, payment policies and coding rules;
- improved medical record documentation;
- improved education for practice employees;
- reduction in the denial of claims;
- more streamlined practice operations through better communication and more comprehensive policies;
- the avoidance of potential liability arising from noncompliance; and
- reduced exposure to penalties.

An effective compliance program is essential for physician practices. With the development of a formal program, Galen may find it easier to comply with its affirmative duty to ensure the accuracy of claims submitted for reimbursement.

B. The Difference Between "Fraudulent" and "Erroneous" Claims To Federal Health Programs

The government realizes that there are significant misunderstandings among physicians regarding the critical differences between "fraudulent" (intentionally or recklessly false) health care claims on the one hand and innocent "erroneous" claims on the other. Some medical providers feel that Federal law enforcement agencies have maligned medical professionals and are focused on innocent billing errors. These individuals are under the impression that innocent billing errors can subject them to civil penalties, or even jail. These feelings and impressions are mistaken and need to be corrected.

To these concerns, the government has set forth the following points. First, the government does not disparage physicians, other medical professionals or medical enterprises. In their view, the great majority of medical professionals are working ethically to render high quality medical care to Medicare beneficiaries and to submit proper claims to Medicare.

Second, under the law, physicians are not subject to civil or criminal penalties for innocent errors, or even negligence. The Government's primary enforcement tool, the civil False Claims Act, covers only offenses that are committed with *actual knowledge* of the falsity of the claim, *reckless disregard*, or *deliberate ignorance* of the falsity of the claim. The False Claims Act

simply does not cover mistakes, errors, or negligence. The other major civil remedy available to the Federal Government, the Civil Monetary Penalties Law, has exactly the same standard of proof. The government has stated that it is very mindful of the difference between innocent errors ("erroneous claims") on one hand, and reckless or intentional conduct ("fraudulent claims") on the other. For criminal penalties, the standard is higher i.e. criminal intent to defraud must be proved beyond a reasonable doubt. The Attorney General of the United States has stated, "it is not the [Justice Department's] policy to punish honest billing mistakes . . . [or] mere negligence. . . . These are not cases where we are seeking to punish someone for honest billing mistakes."

Third, even ethical physicians (and their staffs) make billing mistakes and errors through inadvertence or negligence. When billing errors, honest mistakes, or negligence result in erroneous claims, the government expects the physician practice to return the funds erroneously claimed, but without penalties. In other words, erroneous claims result only in the return of funds claimed in error.

Fourth, innocent billing errors are a significant drain on the programs and all parties (physicians, providers, carriers, fiscal intermediaries, Government agencies, and beneficiaries) need to work cooperatively to reduce the overall error rate. But again, it is emphasized by the government that civil or criminal penalty action will not be initiated with respect to billing errors due to inadvertence or negligence, or for billings based on a negligent medical judgment.

Finally, it is reasonable for physicians (and other providers) to ask: what duty do they owe the Federal health care programs? The answer is that all health care providers have a duty to reasonably ensure that the claims submitted to Medicare and other Federal health care programs are true and accurate. The government continues to engage the provider community in an extensive, good faith effort to work cooperatively on voluntary compliance to minimize errors and to prevent potential penalties for improper billings before they occur. To that end, the government has directed the implementation of compliance programs for the majority of health care providers.

II. COMPLIANCE PROGRAM ELEMENTS

The Seven Basic Compliance Elements

The federal government has set forth seven basic elements necessary for an “effective” compliance program. Regulations state:

An effective program to prevent and detect violations of law means a program that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal conduct. Failure to prevent or detect the instant offense, by itself, does not mean that the program was not effective. The hallmark of an effective program to prevent and detect violations of law is that the organization exercised due diligence in seeking to prevent and detect criminal conduct by its employees and other agents. Due diligence requires, at a minimum, that the organization must have taken the following types of steps:

1. ***Auditing & Monitoring***

The practice must have taken reasonable steps to achieve compliance by conducting internal auditing and monitoring through the performance of periodic audits.

2. ***Practice Standards & Procedures***

The practice must have established compliance standards through the development of a written practice policies and procedures.

3. ***Designation of a Compliance Officer/Contact***

Specific individual(s) within the practice must have been assigned overall responsibility to oversee compliance with the specific practice standards and procedures.

4. ***Training***

The practice must have taken steps to communicate effectively, via comprehensive training, its standards, procedures, policies and practice ethics to all employees and other agents.

5. ***Response & Correction***

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

6. ***Open Lines of Communication***

The practice must have developed accessible lines of communication, such as discussions at staff meetings regarding fraudulent or erroneous conduct issues and community bulletin boards, to keep practice employees updated regarding compliance activities.

7. ***Enforcement & Discipline***

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

STEP ONE: AUDITING AND MONITORING

An ongoing evaluation process is important to a successful compliance program. This ongoing evaluation will include not only whether the practice's standards and procedures are in fact current and accurate, but also whether or not the compliance program is effective, *i.e.*, whether individuals are properly carrying out their responsibilities and claims are submitted appropriately.

1. Practice Policies and Procedures

The individual(s) in charge of the compliance program will be charged with the responsibility of periodically reviewing the policies and procedures of the practice to see if they are current and complete. If the practice policies and procedures are found to be ineffective or outdated, they will be updated to reflect changes in CPT codes and Government regulations.

2. Claims Submission Audit

In addition to the policies and procedures themselves, bills and medical records will be reviewed for compliance with applicable coding, billing and documentation requirements. The people involved in these self-audits will include the person in charge of billing compliance and a medically trained person (*e.g.*, registered nurse or preferably a physician (physicians can rotate in this position)). In the Third-Party Medical Billing Compliance Program Guidance, the OIG recommended that a baseline, or "snapshot," be used as part of the benchmarking analysis that would enable a practice to judge its progress in reducing or eliminating potential areas of vulnerability.

Galen's self-audits will be used to determine whether:

- bills are accurately coded and accurately reflect the services provided;
- services or items provided are reasonable and necessary;
- any incentives for unnecessary services exist; and
- medical records contain sufficient documentation to support the charge.

A baseline audit will examine the claim development and submission process, from patient intake through claim submission and payment, and identify elements within this process that may contribute to non-compliance or that may need to be the focus for improving execution. This audit will establish a consistent methodology for selecting and examining records, and this methodology will serve as a basis for future audits. It will be conducted based on claims submitted during the initial three months after implementation of the education and training program so as to give the physician practice a benchmark against which to measure future compliance effectiveness.

Following the baseline audit, periodic audits will be conducted at least once each year to ensure that our compliance program is being followed. A randomly selected number of medical records might be reviewed to ensure that the coding was performed accurately. Although there is no set

formula to how many medical records will be reviewed, a basic guide is two to five medical records per payer, or five to ten medical records per physician. Of course, the larger the sample size, the greater the confidence in the results. If problems are identified, a focused review should be conducted on a more frequent basis. When audit results reveal areas needing additional information or education of employees and physicians, these areas will be incorporated into the training and educational system.

Periodic audits might include the following:

- a valid sample of the practice's top ten denials, or the practice's top ten services provided;
- confirmation that the practice has been using specific codes, as some codes are too general for "reasonable and necessary" purposes;
- a check for data entry errors;
- confirmation that all orders are written and signed by a physician;
- a check for reasonable and necessary services performed; confirmation that all tests ordered by the physician(s) were actually performed and documented and that only those tests were billed; and
- a review of assignment codes and modifiers to the claims.

One of the most important elements of a successful billing compliance program is appropriate action when the practice identifies a problem in its internal audit. This action should be taken as soon as possible, but it is recommended that the action be taken within 60 days from the date the problem is identified. The specific action that Galen takes will depend on the circumstances of the situation it has identified. In some cases, the action may be as simple as generating a repayment to Medicare or the appropriate payer. Alternatively, the repayment could be effectuated through offsets to other billings, such as undercodings. In others, Galen may want to seek legal advice and/or consult with a coding/billing expert to determine the next best course of action. There is no boilerplate solution to how to handle problems that are identified.

It is important that Galen monitor its billing program to ensure claims are correctly submitted. If the practice identifies, through its internal audits, what may be a potential problem, there should be sufficient confidence in the compliance procedures developed by the practice to reasonably believe that the problem is in fact a potential issue. Steps should be taken to remedy the situation immediately.

STEP TWO: PRACTICE STANDARDS AND PROCEDURES

1. Code of Conduct

The following statement of practice policy constitutes the Code of Conduct of Galen. It affirms Galen's corporate policy of conducting its business and operations in accordance with both the law and the highest standards of business ethics.

- a. The practice requires all employees' compliance with all laws and regulations to which Galen is subject. When the application of a law or regulation is uncertain, the guidance and advice of Galen's Director of Compliance shall be sought.
- b. The practice is dedicated to providing medically necessary health care to patients without regard to race, creed, color, national origin, gender, or disability. Treatment decisions will be made in accordance with clinical need and with applicable laws and regulations.
- c. It is our policy to maintain contacts with governmental officials and other government personnel, whether directly or indirectly, as proper business relationships. Such contacts must never suggest undue influence upon such persons or cast doubt on Galen's integrity. Furthermore, Galen is committed to ensuring the accuracy of all filings with the government.
- d. Galen maintains accurate and reliable corporate records which disclose all disbursements and other transactions to which the practice is a party.
- e. Galen requires the undivided loyalty of its employees in the exercise of their practice responsibilities. Except as may be approved otherwise by the practice or an appropriate committee thereof, personal investments or other activities which may create, or give the appearance of, a conflict of interest are to be avoided.

Galen has adopted the foregoing Code of Conduct to apply to the practice. All employees are expected to adhere to its terms.

2. Practice Policies and Procedures

Galen has complete confidence in the integrity and ethical conduct of its partners, employees and subcontracted physicians. To fortify existing conduct, Galen has decided to publish pertinent "Compliance Policies and Procedures" in order to assist all partners, employees and subcontracted physicians in avoiding both the fact and appearance of improper activities. The Policies and Procedures should be a guide post in assuring that all applicable laws and regulations are understood and followed.

The Policies and Procedures will be distributed to all partners, employees and subcontracted physicians. All partners, employees and subcontracted physicians will be required to certify that

they have read, and fully understand, the Policies and Procedures. Certifications for all partners, employees and subcontracted physicians certifications will be kept on file in a location as directed by the Director of Compliance. Furthermore, adherence to compliance will be an element in evaluating physicians and employees.

3. Specific Risk Areas

Galen is committed to conducting its business in a lawful and ethical manner. Galen's partners and subcontracted physicians are required to comply with all applicable laws, regulations, and policies affecting the operations of the practice (some of which are discussed in Appendix C - Additional Risk Areas), including but no limited to rules relating to:

a. Coding and Billing

The identification of risk areas associated with coding and billing is a major part of Galen's compliance program.

The following risk areas associated with billing have been among the most frequent subjects of investigations and audits by the government:

- billing for items or services not rendered or not provided as claimed;
- submitting claims for equipment, medical supplies and services that are not reasonable and necessary;
- double billing;
- billing for non-covered services as if covered;
- knowing misuse of provider identification numbers, which results in improper billing;
- billing for unbundled services;
- failure to properly use coding modifiers;
- upcoding the level of service provided.

b. Reasonable and Necessary Services

Galen's compliance program will attempt to ensure that only claims for services that the physician practice finds to be reasonable and necessary in the particular case are submitted. The government recognizes that physicians should be able to order any tests, including screening tests, they believe are appropriate for the treatment of their patients. However, the practice should be aware that Medicare will only pay for services that meet the Medicare definition of reasonable and necessary.

Medicare (and many insurance plans) may deny payment for a service that the physician believes is clinically appropriate, but which is not reasonable and necessary. Thus, when a physician provides services to a patient, he or she should only bill those services believed to be reasonable and necessary for the diagnosis and treatment of a patient. Upon request, the physician practice

should be able to provide documentation, such as a patient's medical records and physician's orders, to support the appropriateness of a service that the physician has provided.

c. Documentation

Timely, accurate and complete documentation is critical to nearly every aspect of a physician practice. Therefore, one of the most important physician practice compliance issues is the appropriate documentation of diagnosis and treatment. Physician documentation is necessary to determine the appropriate medical treatment for the patient and is the basis for coding and billing determinations. Most importantly, failure to document properly has the potential to compromise good patient care. Thorough and accurate documentation helps to ensure accurate recording and timely transmission of information.

1. Medical Record Documentation

In addition to facilitating high quality patient care, a properly documented medical record verifies and documents precisely what services were actually provided. The medical record may be used to validate: (a) the site of the service; (b) the appropriateness of the services provided; and (c) the accuracy of the billing. Accurate medical record documentation should comply, at a minimum, with the following principles:

- The medical record should be complete and legible;
- The documentation of each patient encounter should include the reason for the encounter; any relevant history; physical examination findings; prior diagnostic test results; assessment, clinical impression, or diagnosis; plan of care; and date and legible identity of the observer;
- If not documented, the rationale for ordering diagnostic and other ancillary services should be easily inferred by an independent reviewer or third party. Past and present diagnoses should be accessible to the treating and/or consulting physician; and
- Appropriate health risk factors should be identified. The patient's progress, his or her response to, and any changes in, treatment, and any revision in diagnosis should be documented.

The CPT and ICD-9-CM codes reported on the health insurance claims form should be supported by documentation in the medical record and the medical chart should contain all required information. Additionally, HCFA and the local carriers should be able to determine who provided the services. These issues can be the root of investigations of inappropriate or erroneous conduct, and have been identified by HCFA and OIG as a leading cause of inappropriate payments.

2. HCFA 1500 Form

Another documentation area that Galen will monitor closely is the proper completion of the HCFA 1500 form. The following practices will help ensure that the form has been properly completed:

- link the diagnosis code with the steps taken to perform an examination and the record of personal history obtained;
- link a single most appropriate diagnosis with the corresponding procedure code;
- use modifiers appropriately; and
- provide Medicare with all information about a patient's other insurance coverage.

d. Kickbacks, Inducements and Self-Referrals

Galen's compliance program will ensure compliance with the anti-kickback statute, and the physician self-referral law. Remuneration for referrals is illegal because it can distort medical decision-making, cause overutilization of services or supplies, increase costs to Federal health care programs, and result in unfair competition by shutting out competitors who are unwilling to pay it. Remuneration for referrals can also affect the quality of patient care by encouraging physicians to order services or supplies based on profit rather than the patients' best medical interests. In particular, arrangements with hospitals, hospices, nursing facilities, home health agencies, durable medical equipment suppliers and vendors are areas of potential concern. In general, the anti-kickback statute prohibits knowing and willfully giving or receiving anything of value to induce referrals of Federal health care program business. It is generally recommended that all business arrangements wherein physician practices refer business to an outside entity should be on a *fair market value* basis. Whenever a physician practice intends to enter into a business arrangement that involves its making referrals, the arrangement should be reviewed by counsel familiar with the anti-kickback statute and physician self-referral statute.

Galen will implement measures to avoid offering inappropriate inducements to patients. Examples of such inducements include routinely waiving coinsurance or deductible amounts without a good faith determination that the patient is in financial need or failing to make reasonable efforts to collect the cost-sharing amount.

Possible risk areas that will be reviewed pursuant to Galen's Compliance Program include:

- financial arrangements with outside entities to whom the practice may refer Federal health care program business;
- joint ventures with entities supplying goods or services to the physician practice or its patients;
- consulting contracts or medical directorships;
- office and equipment leases with entities to which the physician refers; and
- soliciting, accepting or offering any gift or gratuity of more than nominal value to or from those who may benefit from a physician practice's referral of Federal health care program business.

In order to keep current with this area of the law, Galen will attempt to obtain copies, available

on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, of all relevant OIG Special Fraud Alerts and Advisory Opinions that address the application of the anti-kickback and physician self-referral laws to ensure that practice policies reflect current positions and opinions.

4. Retention of Records

Galen maintains a uniform system for record creation, distribution, retention, storage, retrieval, and destruction of documents. The type of documents developed under this system include clinical and medical records, billing, claims documentation, and other financial records, and all records necessary to protect the integrity of the practice's compliance process and confirm the effectiveness of the program, e.g., documentation that physicians were adequately trained, modifications to the compliance program, results of any investigations conducted, self-disclosure, and results of the practice's auditing and monitoring efforts. Under no circumstances may documents relating to a pending investigation or inquiry regarding a report of a possible billing error or an incident of fraud and abuse be destroyed without permission of the Director of Compliance and approval of legal counsel.

While conducting its compliance activities, as well as its daily operations, Galen will attempt to document its efforts to comply with applicable Federal health care program requirements. For example, when the physician practice requests advice from a Government agency (including a Medicare fiscal intermediary or carrier) charged with administering a Federal health care program, the practice will attempt to document and retain a record of the request and any written or oral response. This step is extremely important if Galen intends to rely on that response to guide it in future decisions, actions, or claim reimbursement requests or appeals. A log of oral inquiries between the practice and third parties, such as carrier representatives, will help the practice document its attempts at compliance. In addition, in a subsequent investigation these records may become relevant to the issue of whether the practice's reliance was "reasonable" and whether it exercised due diligence in developing procedures and practices to implement the advice.

The following record retention guidelines will be followed:

- The length of time that a physician's medical record documentation is to be retained and will be determined pursuant to federal and state mandates;
- Medical records will be secured against loss, destruction, unauthorized access, unauthorized reproduction, corruption, or damage; and
- Policies and procedures will stipulate the disposition of medical records in the event the practice is sold or closed.

STEP THREE: DESIGNATION OF A COMPLIANCE OFFICER/CONTACT

Galen appoints Deedra Wilkerson, Galen Assistant Administrator, as its Director of Compliance. The Director of Compliance is responsible for overseeing implementation of this Plan, making recommendations to practice management regarding changes to the practice to enhance compliance, updating the Compliance Program and serving as liaison to the employees and physicians of Galen. The Director of Compliance has the following specific responsibilities:

- overseeing and monitoring the implementation of the compliance program;
- establishing methods, such as periodic audits, to improve the practice's efficiency and quality of services, and to reduce the practice's vulnerability to fraud and abuse;
- periodically revising the compliance program in light of changes in the needs of the practice or changes in the law and in the policies and procedures of Government and private payer health plans;
- developing, coordinating and participating in a training program that focuses on the elements of the compliance program, and seeks to ensure that training materials are appropriate;
- ensuring that the HHS-OIG's List of Excluded Individuals and Entities, and the General Services Administration's List of Parties Debarred from Federal Programs have been checked with respect to all employees, medical staff and independent contractors;
- ensuring that employees and physicians know, and comply with, pertinent Federal and State statutes, regulations and standards; and
- investigating any report or allegation concerning possible unethical or improper business practices, and monitoring subsequent corrective action and/or compliance.

STEP FOUR: CONDUCTING EFFECTIVE TRAINING AND EDUCATION

Education is an important part of Galen's compliance program. Education programs will be tailored to the practice's needs and include both compliance and specific training.

There are three basic steps that will comprise the practice's educational objectives:

- determining who needs training (both in coding and billing and in compliance);
- determining the type of training that best suits the practice's needs (*e.g.*, seminars, in-service training, self-study or other programs); and
- determining when the education is needed and how much each person should receive.

Training will be accomplished through a variety of means, including in-person training sessions (*i.e.*, either on site or at outside seminars), distribution of newsletters, or even a readily accessible office bulletin board. Regardless of the training modality used, Galen will ensure that the necessary education is communicated effectively. Simply providing individuals with documents for their own reading and comprehension will not be considered sufficient.

1. Compliance Training

Under the direction of the designated compliance officer/contact, both initial and recurrent training in compliance will be required, both with respect to the compliance program itself and applicable statutes and regulations. The operation and importance of the compliance program, the consequences of violating the policies set forth in the program, and the role of each employee in the operation of the compliance program will also be addressed.

Compliance training will have two goals: (1) all employees will receive training on how to perform their jobs in compliance with the standards of the practice and any applicable regulations; and (2) each employee should understand that compliance is a condition of continued employment. Compliance training will center on explaining why the practice is developing and establishing a code of conduct and written policies and procedures. The training will emphasize that following the policies will not get a practice employee in trouble, but violating the policies will. New employees will be trained on the compliance program within 60 days of their start date and such training will be documented. Thereafter, employees should receive refresher training on an annual basis or as appropriate.

2. Coding and Billing Training

Coding and billing training on the Federal health care program requirements may be necessary for certain members of the physician practice staff depending on their respective responsibilities. Individuals who are directly involved with billing, coding or other aspects of the Federal health

care programs will receive extensive education specific to that individual's responsibilities. Items that may be discussed relative to coding and billing training might include:

- coding requirements;
- claim development and submission processes;
- marketing practices that reflect current legal and program standards;
- the ramifications of submitting a claim for physician services when rendered by a non-physician;
- signing a form for a physician without the physician's authorization;
- the ramifications of altering medical records;
- proper documentation of services rendered;
- how to report misconduct;
- proper billing standards and procedures and submission of accurate bills for services or items rendered to Federal health care program beneficiaries;
- the personal obligation of each person involved in the billing process to ensure claims are properly and accurately submitted;
- the legal sanctions for submitting deliberately false or reckless billings;
- informing physicians that they cannot receive payment or any type of incentive to induce referrals and that claims should not be submitted for physician services when those services are rendered by a non-physician (unless they follow the applicable Federal health care program requirements, *e.g.*, "incident to" rules).

3. Format of the Training Program

Training may be conducted either in-house or by an outside source. Training at outside seminars, instead of internal programs and in-service sessions, can be an effective way to achieve the practice's training goals.

As part of the training, Galen will make sure all employees are familiar with at least pertinent risk areas (some of which are detailed herein) and topics of particular OIG interest as identified in the OIG's Work Plan published each year. Galen will also work with its third-party billing company, if one is used, to ensure that documentation is of a level that is adequate for the billing company to submit accurate claims on behalf of the physician practice. In addition to the billing training, Galen will be certain that updated ICD-9, HCPCS and CPT manuals (in addition to the carrier bulletins construing those sources) are available to all employees involved in the billing process. A source of continuous updates on current billing policies will also be readily available.

Galen will not require separate education and training programs for both the compliance and coding and billing training. All in-service training and continuing education should integrate compliance issues, as well as other core values adopted by the practice, such as quality improvement and improved patient service.

4. Continuing Education on Compliance Issues

There is no set formula for determining how often training sessions should occur. The government recommends that there be at least an annual training program for all individuals involved in the coding and billing aspects of the practice. New billing and coding employees will be trained within 60 days of assuming their duties and will work under an experienced employee until their training has been completed.

STEP FIVE: RESPONDING TO DETECTED OFFENSES AND DEVELOPING CORRECTIVE ACTION INITIATIVES

Violations of Galen's compliance program, significant failures to comply with applicable Federal or State law, and other types of misconduct threaten the practice's status as a reliable, honest, and trustworthy provider of health care. Fraudulent or erroneous conduct that has been detected, but not corrected, can seriously endanger the reputation and legal status of the Galen. Consequently, upon receipt of reports or reasonable indications of suspected noncompliance, it is important that the compliance officer or other practice employee investigate the allegations to determine whether a material violation of applicable law or the requirements of the compliance program has occurred, and, if so, take decisive steps to correct the problem.

There are several key warning signs of when a compliance program is not working well, e.g., high rates of rejected and/or suspended claims and the placement of a practice on pre-payment review by the carrier. These warning signs will be followed up on immediately and the compliance procedures of the practice changed to prevent the problem from recurring.

As previously stated, Galen will take appropriate corrective action, including prompt identification of any overpayment to the affected payer. A knowing and willful failure to disclose overpayments within a reasonable period of time could be interpreted as an attempt to conceal the overpayment from the Government, thereby establishing an independent basis for a criminal violation with respect to the physician practice, as well as any individual who may have been involved. For this reason, overpayments should be promptly disclosed and returned to the entity that made the erroneous payment.

After an offense has been detected, Galen will take all reasonable steps to respond to the offense and to prevent similar offenses. The compliance officer will undertake a full internal investigation of all reports of detected violations. The goodwill generated by the development of our compliance program will quickly dissipate if the practice ignores reports of possible fraudulent activity.

Galen's Compliance Program includes provisions that ensure that a violation is not compounded once discovered. The individuals involved in the violation will either be retrained, or, if appropriate, terminated. Galen may also prevent the compounding of the violation by conducting a review of all confirmed violations, and, if appropriate, self-report the violations to the applicable authority.

STEP SIX: DEVELOPING EFFECTIVE LINES OF COMMUNICATION

An open line of communication is essential to proper implementation of an effective compliance program. The OIG has encouraged the use of several forms (*e.g.*, hotlines and e-mail) of communication between the compliance officer/committee and provider personnel.

Galen's compliance program system for effective communication will include the following:

- the requirement that employees report conduct that a reasonable person would, in good faith, believe to be fraudulent or erroneous;
- creation of a user-friendly process, such as an anonymous drop box or hotline, for effectively reporting fraudulent or erroneous conduct;
- provisions in the policies and procedures that state that a failure to report fraudulent or erroneous conduct is a violation of the compliance program;
- development of a simple and readily accessible procedure to process reports of fraudulent or erroneous conduct;
- utilization of a process that maintains the confidentiality of the persons involved in the alleged fraudulent or erroneous conduct and the person making the allegation; and
- provisions in the policies and procedures that there will be no retribution for reporting conduct that a reasonable person acting in good faith would have believed to be fraudulent or erroneous.

The OIG recognizes that protecting anonymity may be infeasible. However, the OIG believes all practice employees, when seeking answers to questions or reporting potential instances of fraudulent or erroneous conduct, should know to whom to turn for assistance in these matters and should be able to do so without fear of retribution. While Galen will strive to maintain the confidentiality of an employee's identity, it should be known that there may be a point at which the individual's identity may become known or may have to be revealed in certain instances.

1. Hotline and Other Mechanisms for Reporting Violations

All Galen physicians, employees and subcontractors are required to report incidents of violations of this Plan, unethical conduct, or incidents or potential fraud and abuse to the Director of Compliance. Such reports may be made in person, through Galen's ComplianceLine (423-954-9011), e-mail (dwilkerson@galenmedical.com) or other forms of written communication. Reports will be treated as confidential to the extent reasonably possible.

2. Protection of Employees

It is the policy of Galen that no employee shall be punished solely on the basis that he or she reported what he or she reasonably believed to be an act of wrongdoing or a violation of this Plan

or the practice's Code of Ethics. Furthermore, Galen is committed to following the protections set forth by federal law.

However, an employee will be subject to disciplinary action if Galen reasonably concludes that the report of wrongdoing was knowingly fabricated by the employee or was knowingly distorted, exaggerated or minimized to either injure someone else or to protect himself or herself.

In determining what, if any, disciplinary action may be taken against an employee, Galen will take into account an employee's own admissions of wrongdoing; provided, however, that the employee's admission was not previously known to the practice or its discovery was not imminent, and that the admission was complete and truthful. An employee whose report of misconduct contains admissions of personal wrongdoing will not be guaranteed protection from disciplinary action, however. The weight to be given the self-confession will depend on all the facts known to Galen at the time it makes its disciplinary decisions.

STEP SEVEN: ENFORCING STANDARDS THROUGH WELL-PUBLICIZED DISCIPLINARY GUIDELINES

Galen's enforcement and disciplinary policies will ensure that violations of the practice's compliance policies will result in consistent and appropriate sanctions, including the possibility of termination, against the offending individual. At the same time, the practice's enforcement and disciplinary procedures will be flexible enough to account for mitigating or aggravating circumstances. Individuals who fail to detect or report violations of the compliance program may also be subject to discipline. Disciplinary actions may include: warnings (oral); reprimands (written); probation; demotion; temporary suspension; discharge of employment; restitution of damages; and referral for criminal prosecution.

Any communication resulting in the finding of non-compliant conduct will be documented in the compliance files by including the date of incident, name of the reporting party, name of the person responsible for taking action, and the follow-up action taken. Galen will conduct checks to make sure all current and potential practice employees are not listed on the OIG or GSA lists of individuals excluded from participation in Federal health care or Government procurement programs.

III. DEPARTING EMPLOYEES - EXIT INTERVIEW

All departing employees must submit to an Exit Interview. One of the purposes of the Exit Interview is to determine if the employee has knowledge of any wrongdoing, unethical behavior or criminal conduct. The interview also may be used to obtain information about unsafe or unsound business practices and the like. The interview will be conducted while the employee is still on the payroll and on Galen property. The interview should be conducted by someone other than the departing employee's immediate supervisor. The preferred interviewer should be the Director of Corporate Compliance. The interviewer should prepare a report of the Exit Interview with the employee's answers duly noted. The report, if negative, should be made a part of the employee's personnel file. If any affirmative answers are given, or if the interviewer is otherwise concerned about the employee's honesty, the Director of Compliance should be notified immediately. (See Appendix A for an outline of potential questions to be utilized during the exit interview.)

IV. GOVERNMENT INVESTIGATIONS

If any physician or employee of the practice is contacted (e.g., inquiry, subpoena, personal visit) by a governmental agency regarding Galen business, Galen partners, employees and subcontractors are required to notify the Director of Compliance immediately. While it is practice policy to cooperate with governmental agencies, Galen's legal rights must be protected. In the case where a governmental agent visits an employee, partner or subcontractor, the agent should be asked to contact the Director of Compliance to arrange an interview. The Director of Compliance, in turn, will notify legal counsel to discuss the matter. (See Appendix B for information on the rights and obligations of interviewed individuals.)

V. REPORTING INTENTIONAL WRONGDOING TO AUTHORITIES

It shall be Galen's policy to carefully evaluate all allegations of wrongdoing to determine: (1) if the allegation appears to be well-founded and (2) whether the allegation warrants reporting to enforcement authorities. When billing errors have been reported and payments returned, unless there is evidence of a pattern or an attempt to conceal intentional wrongdoing, no further reporting to enforcement authorities is required.

The Director of Compliance shall consult with any outside experts deemed necessary in order to comply with this policy. Unless immediate reporting is required to prevent personal injury, property damage, bodily harm or damage to the environment, or is otherwise mandated by law, the Director of Compliance will endeavor to consult in advance with practice management before reporting suspected violations of the law to third parties.

If, after a thorough internal investigation, Galen decides to make a report to the authorities, it will assure that:

1. such report is "made under the direction" of Galen and to the appropriate governmental authorities; and
2. such report is "both timely and thorough" as defined by the federal government.

VI. PLAN MODIFICATIONS

It shall be the duty of the Director of Compliance to monitor, on a regular basis, developments in all applicable laws which might affect Galen legal duties under the Plan. If necessary, the Director of Compliance will make appropriate modifications and potential design changes to ensure the continued effectiveness of the practice's plan.

VII. CONCLUSION

Galen has developed and implemented our compliance program to protect against fraudulent or erroneous conduct. We are hopeful that the design and implementation of internal controls and procedures will promote adherence to federal health care program and private insurance program requirements. By implementing an effective compliance program, we can continue to provide quality and compassionate care to our patients.

APPENDIX A: EXIT INTERVIEW QUESTIONNAIRE

The following questions should be included in the Exit Interview, but are in no way meant to be exhaustive. Any affirmative answers should be followed up with detailed questions designed to identify: (1) participants in the conduct, (2) witnesses to the conduct or others with knowledge of the conduct, (3) the date and place of the conduct, (4) location of any documents or physical evidence, and (5) any other information necessary for Galen to either verify or disprove the allegations. In other words, any affirmative answer should result in a request for details.

1. Have you ever engaged in conduct as a Galen employee which you believe was either unethical or illegal?
2. Have you ever been asked to engage in conduct you believe was either unethical or illegal? If so, by whom?
3. Have you ever witnessed conduct by any Galen employee you believe was unethical or illegal?
4. Have you heard substantive rumors or reports (i.e., those you felt had some believability) of unethical or illegal conduct by other Galen employees?
5. Have you ever removed Galen documents (including documents created by you) without returning them to Galen?
6. Do you now have copies of any Galen documents anywhere off premises? Have you ever given Galen documents to any non-Galen employee?
7. Do you know of any Galen employee who has handled company documents in the manner described in questions #5 and #6?
8. Has any government investigator, agent or attorney interviewed you or asked to interview you about possible unethical or illegal conduct related to Galen?
9. While an employee of Galen, did you or any family member own, operate, invest in, assist or otherwise have an interest in any Galen or enterprise which competes with Galen?

Employee Signature

Interview Date: _____

Interview Conducted By:

**APPENDIX B: RIGHTS AND OBLIGATIONS OF Galen PERSONNEL
IF CONTACTED BY A GOVERNMENT ATTORNEY OR AGENT**

Government attorneys, agents, and investigators frequently conduct investigations and inquiries in order to monitor compliance with government regulations and laws. As a result, employees of Galen may be contacted by a government attorney or agent in the course of an investigation. Employees may be contacted either at work or away from work during off hours. As an employee, you have certain rights and obligations of which you should be aware in the event you are contacted by an agent or attorney during the course of an investigation. Please be aware of the following:

- While you are free to talk with government investigators, you are under no obligation to do so.
- You have a right to decline to be interviewed by a government attorney or investigator.
- Absent formal process, government agents or investigators cannot compel you to be interviewed or make a statement.
- You also have a right to choose to speak with a government investigator or agent. If you choose to be interviewed or make a statement, Galen expects you to respond to questions truthfully.
- Regardless of whether you refuse to be interviewed or agree to be interviewed, Galen requests that you inform your supervisor of the date of the contact and the name of the investigator.
- If contacted by a government attorney or agent, you have the right to meet with an attorney. You also have the right to have an attorney present during an interview.
- Galen will provide an attorney to meet with any employee who is contacted during the course of an investigation. If an attorney is requested, the attorney will be able to inform you of the nature of the investigation and your rights in connection with the investigation.

APPENDIX C: ADDITIONAL RISK AREAS

Appendix C describes additional risk areas that a physician practice may wish to address during the development of its compliance program. If any of the following risk areas are applicable to the practice, the practice may want to consider addressing the risk areas by incorporating them into the practice's written standards and procedures manual and addressing them in its training program.

I. Reasonable and Necessary Services

A. Local Medical Review Policy

An area of concern for physicians relating to determinations of reasonable and necessary services is the variation in local medical review policies (LMRPs) among carriers. Physicians are supposed to bill the Federal health care programs only for items and services that are reasonable and necessary. However, in order to determine whether an item or service is reasonable and necessary under Medicare guidelines, the physician must apply the appropriate LMRP.

With the exception of claims that are properly coded and submitted to Medicare solely for the purpose of obtaining a written denial, physician practices are to bill the Federal health programs only for items and services that are covered. In order to determine if an item or service is covered for Medicare, a physician practice must be knowledgeable of the LMRPs applicable to its practice's jurisdiction. The practice may contact its carrier to request a copy of the pertinent LMRPs, and once the practice receives the copies, they can be incorporated into the practice's written standards and procedures manual. When the LMRP indicates that an item or service may not be covered by Medicare, the physician practice is responsible to convey this information to the patient so that the patient can make an informed decision concerning the health care services he/she may want to receive. Physician practices convey this information through Advance Beneficiary Notices (ABNs).

B. Advance Beneficiary Notices

Physicians are required to provide ABNs before they provide services that they know or believe Medicare does not consider reasonable and necessary. (The one exception to this requirement is for services that are performed pursuant to EMTALA requirements as described in section II.A). A properly executed ABN acknowledges that coverage is uncertain or yet to be determined, and stipulates that the patient promises to pay the bill if Medicare does not. Patients who are not notified before they receive such services are not responsible for payment. The ABN must be sufficient to put the patient on notice of the reasons why the physician believes that the payment may be denied. The objective is to give the patient sufficient information to allow an informed choice as to whether to pay for the service.

Accordingly, each ABN should:

1. be in writing;
2. identify the specific service that may be denied (procedure name and CPT/HCPC code is recommended);

APPENDIX C: ADDITIONAL RISK AREAS (continued)

3. state the specific reason why the physician believes that service may be denied; and
4. be signed by the patient acknowledging that the required information was provided and that the patient assumes responsibility to pay for the service.

The Medicare Carrier's Manual provides that an ABN will not be acceptable if: (1) the patient is asked to sign a blank ABN form; or (2) the ABN is used routinely without regard to a particularized need. The routine use of ABNs is generally prohibited because the ABN must state the specific reason the physician anticipates that the specific service will not be covered.

A common risk area associated with ABNs is in regard to diagnostic tests or services. There are three steps that a physician practice can take to help ensure it is in compliance with the regulations concerning ABNs for diagnostic tests or services:

1. determine which tests are not covered under national coverage rules;
2. determine which tests are not covered under local coverage rules such as LMRPs (contact the practice's carrier to see if a listing has been assembled); and
3. determine which tests are only covered for certain diagnoses.

The OIG is aware that the use of ABNs is an area where physician practices experience numerous difficulties. Practices can help to reduce problems in this area by educating their physicians and office staff on the correct use of ABNs, obtaining guidance from the carrier regarding their interpretation of whether an ABN is necessary where the service is not covered, developing a standard form for all diagnostic tests (most carriers have a developed model), and developing a process for handling patients who refuse to sign ABNs.

C. Physician Liability for Certifications in the Provision of Medical Equipment and Supplies and Home Health Services

In January 1999, the OIG issued a Special Fraud Alert on this topic, which is available on the OIG web site at www.hhs.gov/oig/frdalrt/index.htm. The following is a summary of the Special Fraud Alert.

The OIG issued the Special Fraud Alert to reiterate to physicians the legal and programmatic significance of physician certifications made in connection with the ordering of certain items and services for Medicare patients. In light of information obtained through OIG provider audits, the OIG deemed it necessary to remind physicians that they may be subject to criminal, civil and administrative penalties for signing a certification when they know that the information is false or for signing a certification with reckless disregard as to the truth of the information. (See Appendix B and Appendix C for more detailed information on the applicable statutes).

Medicare has conditioned payment for many items and services on a certification signed by a physician attesting that the physician has reviewed the patient's condition and has determined that an item or service is reasonable and necessary. Because Medicare primarily relies on the

APPENDIX C: ADDITIONAL RISK AREAS (continued)

professional judgment of the treating physician to determine the reasonable and necessary nature of a given service or supply, it is important that physicians provide complete and accurate information on any certifications they sign. Physician certification is obtained through a variety of forms, including prescriptions, orders, and Certificates of Medical Necessity (CMNs). Two areas where physician certification as to whether an item or service is reasonable and necessary is essential and which are vulnerable to abuse are: (1) home health services; and (2) durable medical equipment.

By signing a CMN, the physician represents that:

1. he or she is the patient's treating physician and that the information regarding the physician's address and unique physician identification number (UPIN) is correct;
2. the entire CMN, including the sections filled out by the supplier, was completed prior to the physician's signature; and
3. the information in section B relating to whether the item or service is reasonable and necessary is true, accurate, and complete to the best of the physician's knowledge.

Activities such as signing blank CMNs, signing a CMN without seeing the patient to verify the item or service is reasonable and necessary, and signing a CMN for a service that the physician knows is not reasonable and necessary are activities that can lead to criminal, civil and administrative penalties.

Ultimately, it is advised that physicians carefully review any form of certification (order, prescription or CMN) before signing it to verify that the information contained in the certification is both complete and accurate.

D. Billing for Non-covered Services as if Covered

In some instances, we are aware that physician practices submit claims for services in order to receive a denial from the carrier, thereby enabling the patient to submit the denied claim for payment to a secondary payer.

A common question relating to this risk area is: If the medical services provided are not covered under Medicare, but the secondary or supplemental insurer requires a Medicare rejection in order to cover the services, then would the original submission of the claim to Medicare be considered fraudulent? Under the applicable regulations, the OIG would not consider such submissions to be fraudulent. For example, the denial may be necessary to establish patient liability protections as stated in section 1879 of the Social Security Act (the Act) (codified at 42 U.S.C. 1395pp). As stated, Medicare denials may also be required so that the patient can seek payment from a secondary insurer. In instances where a claim is being submitted to Medicare for this purpose, the physician should indicate on the claim submission that the claim is being submitted for the purpose of receiving a denial, in order to bill a secondary insurance carrier. This step should assist carriers and prevent inadvertent payments to which the physician is not entitled.

APPENDIX C: ADDITIONAL RISK AREAS (continued)

In some instances, however, the carrier pays the claim even though the service is non-covered, and even though the physician did not intend for payment to be made. When this occurs, the physician has a responsibility to refund the amount paid and indicate that the service is not covered.

II. Physician Relationships with Hospitals

A. The Physician Role in EMTALA

The Emergency Medical Treatment and Active Labor Act (EMTALA), 42 U.S.C. 1395dd, is an area that has been receiving increasing scrutiny. The statute is intended to ensure that all patients who come to the emergency department of a hospital receive care, regardless of their insurance or ability to pay. Both hospitals and physicians need to work together to ensure compliance with the provisions of this law.

The statute imposes three fundamental requirements upon hospitals that participate in the Medicare program with regard to patients requesting emergency care. First, the hospital must conduct an appropriate medical screening examination to determine if an emergency medical condition exists. Second, if the hospital determines that an emergency medical condition exists, it must either provide the treatment necessary to stabilize the emergency medical condition or comply with the statute's requirements to effect a proper transfer of a patient whose condition has not been stabilized. A hospital is considered to have met this second requirement if an individual refuses the hospital's offer of additional examination or treatment, or refuses to consent to a transfer, after having been informed of the risks and benefits.

If an individual's emergency medical condition has not been stabilized, the statute's third requirement is activated. A hospital may not transfer an individual with an unstable emergency medical condition unless: (1) the individual or his or her representative makes a written request for transfer to another medical facility after being informed of the risk of transfer and the transferring hospital's obligation under the statute to provide additional examination or treatment; (2) a physician has signed a certification summarizing the medical risks and benefits of a transfer and certifying that, based up on the information available at the time of transfer, the medical benefits reasonably expected from the transfer outweigh the increased risks; or (3) if a physician is not physically present when the transfer decision is made, a qualified medical person signs the certification after the physician, in consultation with the qualified medical person, has made the determination that the benefits of transfer outweigh the increased risks. The physician must later countersign the certification.

Physician and/or hospital misconduct may result in violations of the statute. One area of particular concern is physician on-call responsibilities. Physician practices whose members serve as on-call emergency room physicians with hospitals are advised to familiarize themselves with the hospital's policies regarding on-call physicians. This can be done by reviewing the medical staff bylaws or policies and procedures of the hospital that must define the responsibility of on-

APPENDIX C: ADDITIONAL RISK AREAS (continued)

call physicians to respond to, examine, and treat patients with emergency medical conditions. Physicians should also be aware of the requirement that, when medically indicated, on-call physicians must generally come to the hospital to examine the patient. The exception to this requirement is that a patient may be sent to see the on-call physician at a hospital-owned contiguous or on-campus facility to conduct or complete the medical screening examination as long as:

1. all persons with the same medical condition are moved to this location;
2. there is a bona fide medical reason to move the patient; and
3. qualified medical personnel accompany the patient.

B. Teaching Physicians

Special regulations apply to teaching physicians' billings. Regulations provide that services provided by teaching physicians in teaching settings are generally payable under the physician fee schedule only if the services are personally furnished by a physician who is not a resident or the services are furnished by a resident in the presence of a teaching physician.

Unless a service falls under a specified exception, such as the Primary Care Exception, the teaching physician must be present during the key portion of any service or procedure for which payment is sought. Physicians should ensure the following with respect to services provided in the teaching physician setting:

- only services actually provided are billed;
- every physician who provides or supervises the provision of services to a patient is responsible for the correct documentation of the services that were rendered;
- every physician is responsible for assuring that in cases where the physician provides evaluation and management (E&M) services, a patient's medical record includes appropriate documentation of the applicable key components of the E&M services provided or supervised by the physician (e.g., patient history, physician examination, and medical decision making), as well as documentation to adequately reflect the procedure or portion of the services provided by the physician; and
- unless specifically excepted by regulation, every physician must document his or her presence during the key portion of any service or procedure for which payment is sought.

C. Gainsharing Arrangements and Civil Monetary Penalties for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries

In July 1999, the OIG issued a Special Fraud Alert on this topic, which is available on the OIG web site at www.hhs.gov/oig/frdalrt/index.htm. The following is a summary of the Special Fraud Alert. The term "gainsharing" typically refers to an arrangement in which a hospital gives a

APPENDIX C: ADDITIONAL RISK AREAS (continued)

physician a percentage share of any reduction in the hospital's costs for patient care attributable in part to the physician's efforts. The civil monetary penalty (CMP) that applies to gainsharing arrangements is set forth in 42 U.S.C. 1320a-7a(b)(1). This section prohibits any hospital or critical access hospital from knowingly making a payment directly or indirectly to a physician as an inducement to reduce or limit services to Medicare or Medicaid beneficiaries under a physician's care.

It is the OIG's position that the Civil Monetary Penalties Law clearly prohibits any gainsharing arrangements that involve payments by, or on behalf of, a hospital to physicians with clinical care responsibilities to induce a reduction or limitation of services to Medicare or Medicaid beneficiaries. However, hospitals and physicians are not prohibited from working together to reduce unnecessary hospital costs through other arrangements. For example, hospitals and physicians may enter into personal services contracts where hospitals pay physicians based on a fixed fee at fair market value for services rendered to reduce costs rather than a fee based on a share of cost savings.

D. Physician Incentive Arrangements

The OIG has identified potentially illegal practices involving the offering of incentives by entities in an effort to recruit and retain physicians. The OIG is concerned that the intent behind offering incentives to physicians may not be to recruit physicians, but instead the offer is intended as a kickback to obtain and increase patient referrals from physicians. These recruitment incentive arrangements are implicated by the Anti-Kickback Statute because they can constitute remuneration offered to induce, or in return for, the referral of business paid for by Medicare or Medicaid.

Some examples of questionable incentive arrangements are:

- provision of free or significantly discounted billing, nursing, or other staff services.
- payment of the cost of a physician's travel and expenses for conferences.
- payment for a physician's services that require few, if any, substantive duties by the physician.
- guarantees that if the physician's income fails to reach a predetermined level, the entity will supplement the remainder up to a certain amount.

III. Physician Billing Practices

A. Third-Party Billing Services

Physicians should remember that they remain responsible to the Medicare program for bills sent in the physician's name or containing the physician's signature, even if the physician had no actual knowledge of a billing impropriety. The attestation on the HCFA 1500 form, *i.e.*, the physician's signature line, states that the physician's services were billed properly. In other

APPENDIX C: ADDITIONAL RISK AREAS (continued)

words, it is no defense for the physician if the physician's billing service improperly bills Medicare.

One of the most common risk areas involving billing services deals with physician practices contracting with billing services on a percentage basis. Although percentage based billing arrangements are not illegal per se, the Office of Inspector General has a longstanding concern that such arrangements may increase the risk of intentional upcoding and similar abusive billing practices.

A physician may contract with a billing service on a percentage basis. However, the billing service can not directly receive the payment of Medicare funds into a bank account that it solely controls. Under 42 U.S.C. 1395u(b)(6), Medicare payments can only be made to either the beneficiary or a party (such as a physician) that furnished the services and accepted assignment of the beneficiary's claim. A billing service that contracts on a percentage basis does not qualify as a party that furnished services to a beneficiary, thus a billing service cannot directly receive payment of Medicare funds. According to the Medicare Carriers Manual § 3060(A), a payment is considered to be made directly to the billing service if the service can convert the payment to its own use and control without the payment first passing through the control of the physician. For example, the billing service should not bill the claims under its own name or tax identification number. The billing service should bill claims under the physician's name and tax identification number. Nor should a billing service receive the payment of Medicare funds directly into a bank account over which the billing service maintains sole control. The Medicare payments should instead be deposited into a bank account over which the provider has signature control.

Physician practices should review the third-party medical billing guidance for additional information on third-party billing companies and the compliance risk areas associated with billing companies.

B. Billing Practices by Non-Participating Physicians

Even though nonparticipating physicians do not accept payment directly from the Medicare program, there are a number of laws that apply to the billing of Medicare beneficiaries by non-participating physicians.

Limiting Charges

42 U.S.C. 1395w-4(g) prohibits a nonparticipating physician from knowingly and willfully billing or collecting on a repeated basis an actual charge for a service that is in excess of the Medicare limiting charge. For example, a nonparticipating physician may not bill a Medicare beneficiary \$50 for an office visit when the Medicare limiting charge for the visit is \$25.

APPENDIX C: ADDITIONAL RISK AREAS (continued)

Additionally, there are numerous provisions that prohibit nonparticipating physicians from knowingly and willfully charging patients in excess of the statutory charge limitations for certain specified procedures, such as cataract surgery, mammography screening and coronary artery bypass surgery. Failure to comply with these sections can result in a fine of up to \$10,000 per violation or exclusion from participation in Federal health care programs for up to five years.

Refund of Excess Charges

42 U.S.C. 1395w-4(g) mandates that if a nonparticipating physician collects an actual charge for a service that is in excess of the limiting charge, the physician must refund the amount collected above the limiting charge to the individual within 30 days notice of the violation. For example, if a physician collected \$50 from a Medicare beneficiary for an office visit, but the limiting charge for the visit was \$25, the physician must refund \$25 to the beneficiary, which is the difference between the amount collected (\$50) and the limiting charge (\$25). Failure to comply with this requirement may result in a fine of up to \$10,000 per violation or exclusion from participation in Federal health care programs for up to five years.

42 U.S.C. 1395u(l)(A)(iii) mandates that a nonparticipating physician must refund payments received from a Medicare beneficiary if it is later determined by a Peer Review Organization or a Medicare carrier that the services were not reasonable and necessary. Failure to comply with this requirement may result in a fine of up to \$10,000 per violation or exclusion from participation in Federal health care programs for up to five years.

C. Professional Courtesy

The term “professional courtesy” is used to describe a number of analytically different practices. The traditional definition is the practice by a physician of waiving all or a part of the fee for services provided to the physician’s office staff, other physicians, and/or their families. In recent times, “professional courtesy” has also come to mean the waiver of coinsurance obligations or other out-of-pocket expenses for physicians or their families (i.e., “insurance only” billing), and similar payment arrangements by hospitals or other institutions for services provided to their medical staffs or employees. While only the first of these practices is truly “professional courtesy”, in the interests of clarity and completeness, we will address all three.

In general, whether a professional courtesy arrangement runs afoul of the fraud and abuse laws is determined by two factors: (i) how the recipients of the professional courtesy are selected; and (ii) how the professional courtesy is extended. If recipients are selected in a manner that directly or indirectly takes into account their ability to affect past or future referrals, the anti-kickback statute -- which prohibits giving anything of value to generate Federal health care program business -- may be implicated. If the professional courtesy is extended through a waiver of copayment obligations (i.e., “insurance only” billing), other statutes may be implicated,

APPENDIX C: ADDITIONAL RISK AREAS (continued)

including the prohibition of inducements to beneficiaries, section 1128A(a)(5) of the Act (codified at 42 U.S.C. 1320a-7a(a)(5)). Claims submitted as a result of either practice may also implicate the civil False Claims Act.

The following are general observations about professional courtesy arrangements for physician practices to consider:

- A physician's regular and consistent practice of extending professional courtesy by waiving the entire fee for services rendered to a group of persons (including employees, physicians, and/or their family members) may not implicate any of the OIG's fraud and abuse authorities so long as membership in the group receiving the courtesy is determined in a manner that does not take into account directly or indirectly any group member's ability to refer to, or otherwise generate Federal health care program business for, the physician.
- A physician's regular and consistent practice of extending professional courtesy by waiving otherwise applicable copayments for services rendered to a group of persons (including employees, physicians, and/or their family members), would not implicate the anti-kickback statute so long as membership in the group is determined in a manner that does not take into account directly or indirectly any group member's ability to refer to, or otherwise generate Federal health care program business for, the physician.
- Any waiver of copayment practice, including that described in the preceding bullet, does implicate section 1128A(a)(5) of the Act if the patient for whom the copayment is waived is a Federal health care program beneficiary who is not financially needy.

The legality of particular professional courtesy arrangements will turn on the specific facts presented, and, with respect to the anti-kickback statute, on the specific intent of the parties. A physician practice may wish to consult with an attorney if it is uncertain about its professional courtesy arrangements.

IV. Other Risk Areas

A. Rental of Space in Physician Offices by Persons or Entities to which Physicians Refer

In February 2000, the OIG issued a Special Fraud Alert on this topic, which is available on the OIG web site at www.hhs.gov/oig/frdalrt/index.htm. The following is a summary of the Special Fraud Alert.

Among various relationships between physicians and labs, hospitals, home health agencies, etc., the OIG has identified potentially illegal practices involving the rental of space in a physician's office by suppliers that provide items or services to patients who are referred or sent to the

APPENDIX C: ADDITIONAL RISK AREAS (continued)

supplier by the physician-landlord. An example of a suspect arrangement is the rental of physician office space by a durable medical equipment (DME) supplier in a position to benefit from referrals of the physician's patients. The OIG is concerned that in such arrangements the rental payments may be disguised kickbacks to the physician-landlord to induce referrals.

Space Rental Safe Harbor to the Anti-Kickback Statute

To avoid potentially violating the anti-kickback statute, the OIG recommends that rental agreements comply with all of the following criteria for the space rental safe harbor:

- The agreement is set out in writing and signed by the parties.
- The agreement covers all of the space rented by the parties for the term of the agreement and specifies the space covered by the agreement.
- If the agreement is intended to provide the lessee with access to the space for periodic intervals of time rather than on a full-time basis for the term of the rental agreement, the rental agreement specifies exactly the schedule of such intervals, the precise length of each interval, and the exact rent for each interval.
- The term of the rental agreement is for not less than one year.
- The aggregate rental charge is set in advance, is consistent with fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.
- The aggregate space rented does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

B. Unlawful Advertising

42 U.S.C. 1320b-10 makes it unlawful for any person to advertise using the names, abbreviations, symbols, or emblems of the Social Security Administration, Health Care Financing Administration, Department of Health and Human Services, Medicare, Medicaid or any combination or variation of such words, abbreviations, symbols or emblems in a manner that such person knows or should know would convey the false impression that the advertised item is endorsed by the named entities. For instance, a physician may not place an ad in the newspaper that reads "Dr. X is a cardiologist approved by both the Medicare and Medicaid programs." A violation of this section may result in a penalty of up to \$5,000 (\$25,000 in the case of a broadcast or telecast) for each violation.

APPENDIX D: CRIMINAL STATUTES

This Appendix contains a description of criminal statutes related to fraud and abuse in the context of health care. The Appendix is not intended to be a compilation of all Federal statutes related to health care fraud and abuse. It is merely a summary of some of the more frequently cited Federal statutes.

I. Health Care Fraud (18 U.S.C. 1347)

Description of Unlawful Conduct

It is a crime to knowingly and willfully execute (or attempt to execute) a scheme to defraud any health care benefit program, or to obtain money or property from a health care benefit program through false representations. Note that this law applies not only to Federal health care programs, but to most other types of health care benefit programs as well.

Penalty for Unlawful Conduct

The penalty may include the imposition of fines, imprisonment of up to 10 years, or both. If the violation results in serious bodily injury, the prison term may be increased to a maximum of 20 years. If the violation results in death, the prison term may be expanded to include any number of years, or life imprisonment.

Examples

Dr. X, a chiropractor, intentionally billed Medicare for physical therapy and chiropractic treatments that he never actually rendered for the purposes of fraudulently obtaining Medicare payments.

Dr. X, a psychiatrist, billed Medicare, Medicaid, TRICARE, and private insurers for psychiatric services that were provided by his nurses rather than himself.

II. Theft or Embezzlement in Connection with Health Care (18 U.S.C. 669)

Description of Unlawful Conduct It is a crime to knowingly and willfully embezzle, steal or intentionally misapply any of the assets of a health care benefit program. Note that this law applies not only to Federal health care programs, but to most other types of health care benefit programs as well.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment of up to 10 years, or both. If the value of the asset is \$100 or less, the penalty is a fine, imprisonment of up to a year, or both.

Example

An office manager for Dr. X knowingly embezzles money from the bank account for Dr. X's practice. The bank account includes reimbursement received from the Medicare program; thus, intentional embezzlement of funds from this account is a violation of the law.

APPENDIX D: CRIMINAL STATUTES (continued)

III. False Statements Relating to Health Care Matters (18 U.S.C. 1035)

Description of Unlawful Conduct

It is a crime to knowingly and willfully falsify or conceal a material fact, or make any materially false statement or use any materially false writing or document in connection with the delivery of or payment for health care benefits, items or services. Note that this law applies not only to Federal health care programs, but to most other types of health care benefit programs as well.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment of up to 5 years, or both.

Example

Dr. X certified on a claim form that he performed laser surgery on a Medicare beneficiary when he knew that the surgery was not actually performed on the patient.

IV. Obstruction of Criminal Investigations of Health Care Offenses (18 U.S.C. 1518)

Description of Unlawful Conduct

It is a crime to willfully prevent, obstruct, mislead, delay or attempt to prevent, obstruct, mislead, or delay the communication of records relating to a Federal health care offense to a criminal investigator. Note that this law applies not only to Federal health care programs, but to most other types of health care benefit programs as well.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment of up to 5 years, or both.

Examples

1. Dr. X instructs his employees to tell OIG investigators that Dr. X personally performs all treatments when, in fact, medical technicians do the majority of the treatment and Dr. X is rarely present in the office.
2. Dr. X was under investigation by the FBI for reported fraudulent billings. Dr. X altered patient records in an attempt to cover up the improprieties.

V. Mail and Wire Fraud (18 U.S.C. 1341, 1343)

Description of Unlawful Conduct

It is a crime to use the mail, private courier, or wire service to conduct a scheme to defraud another of money or property. The term "wire services" includes the use of a telephone, fax machine or computer. Each use of a mail or wire service to further fraudulent activities is considered a separate crime. For instance, each fraudulent claim that is submitted electronically to a carrier would be considered a separate violation of the law.

APPENDIX D: CRIMINAL STATUTES (continued)

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment of up to 5 years, or both.

Examples

1. Dr. X knowingly and repeatedly submits electronic claims to the Medicare carrier for office visits that he did not actually provide to Medicare beneficiaries with the intent to obtain payments from Medicare for services he never performed.
2. Dr. X, a neurologist, knowingly submitted claims for tests that were not reasonable and necessary and intentionally upcoded office visits and electromyograms to Medicare.

VI. Criminal Penalties for Acts Involving Federal Health Care Programs (42 U.S.C. 1320a-7b)

Description of Unlawful Conduct

False Statements and Representations

It is a crime to knowingly and willfully:

- make, or cause to be made, false statements or representations in applying for benefits or payments under all Federal health care programs;
- make, or cause to be made, any false statement or representation for use in determining rights to such benefit or payment;
- conceal any event affecting an individual's initial or continued right to receive a benefit or payment with the intent to fraudulently receive the benefit or payment either in an amount or quantity greater than that which is due or authorized;
- convert a benefit or payment to a use other than for the use and benefit of the person for whom it was intended;
- present, or cause to be presented, a claim for a physician's service when the service was not furnished by a licensed physician;
- for a fee, counsel an individual to dispose of assets in order to become eligible for medical assistance under a State health program, if disposing of the assets results in the imposition of an ineligibility period for the individual.

Anti-Kickback Statute

It is a crime to knowingly and willfully solicit, receive, offer, or pay remuneration of any kind (e.g., money, goods, services):

- for the referral of an individual to another for the purpose of supplying items or services that are covered by a Federal health care program; or

APPENDIX D: CRIMINAL STATUTES (continued)

- for purchasing, leasing, ordering, or arranging for any good, facility, service, or item that is covered by a Federal health care program.

There are a number of limited exceptions to the law, also known as "safe harbors," which provide immunity from criminal prosecution and which are described in greater detail in the statute and related regulations (found at 42 CFR 1001.952 and www.hhs.gov/oig/ak). Current safe harbors include:

- investment interests;
- space rental;
- equipment rental;
- personal services and management contracts;
- sale of practice;
- referral services;
- warranties;
- discounts;
- employment relationships;
- waiver of Part A co-insurance and deductible amounts;
- group purchasing organizations;
- increased coverage or reduced cost sharing under a risk-basis or prepaid plan; and
- charge reduction agreements with health plans.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine of up to \$25,000, imprisonment of up to 5 years, or both. In addition, the provider can be excluded from participation in Federal health care programs. The regulations defining the aggravating and mitigating circumstances that must be reviewed by the OIG in making an exclusion determination are set forth in 42 CFR Part 1001.

Examples

1. Dr. X accepted payments to sign Certificates of Medical Necessity for durable medical equipment for patients she never examined.
2. Home Health Agency disguises referral fees as salaries by paying referring physician Dr. X for services Dr. X never rendered to Medicare beneficiaries or by paying Dr. X. a sum in excess of fair market value for the services he rendered to Medicare beneficiaries.

APPENDIX E: CIVIL AND ADMINISTRATIVE STATUTES

This Appendix contains a description of civil and administrative statutes related to fraud and abuse in the context of health care. The Appendix is not intended to be a compilation of all Federal statutes related to health care fraud and abuse. It is merely a summary of some of the more frequently cited Federal statutes.

I. The False Claims Act (31 U.S.C. 3729-3733)

Description of Unlawful Conduct

This is the law most often used to bring a case against a health care provider for the submission of false claims to a Federal health care program. The False Claims Act prohibits knowingly presenting (or causing to be presented) to the Federal Government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the Federal Government or its agents, like a carrier, other claims processor, or state Medicaid program.

Definitions

False Claim - A false claim is a claim for payment for services or supplies that were not provided specifically as presented or for which the provider is otherwise not entitled to payment. Examples of false claims for services or supplies that were not provided specifically as presented include, but are not limited to:

- _ a claim for a service or supply that was never provided.
- _ a claim indicating the service was provided for some diagnosis code other than the true diagnosis code in order to obtain reimbursement for the service (which would not be covered if the true diagnosis code were submitted).
- _ a claim indicating a higher level of service than was actually provided.
- _ a claim for a service that the provider knows is not reasonable and necessary.
- _ a claim for services provided by an unlicensed individual.

Knowingly - To "knowingly" present a false or fraudulent claim means that the provider: 1) has actual knowledge that the information on the claim is false; 2) acts in deliberate ignorance of the truth or falsity of the information on the claim; or 3) acts in reckless disregard of the truth or falsity of the information on the claim. It is important to note the provider does not have to deliberately intend to defraud the Federal Government in order to be found liable under this Act. The provider need only "knowingly" present a false or fraudulent claim in the manner described above.

APPENDIX E: CIVIL AND ADMINISTRATIVE STATUTES (continued)

Deliberate Ignorance - To act in "deliberate ignorance" means that the provider has deliberately chosen to ignore the truth or falsity of the information on a claim submitted for payment, even though the provider knows, or has notice, that information may be false. An example of a provider who submits a false claim with deliberate ignorance would be a physician who ignores provider update bulletins and thus does not inform his/her staff of changes in the Medicare billing guidelines or update his/her billing system in accordance with changes to Medicare billing practices. When claims for non-reimbursable services are submitted as a result, the False Claims Act has been violated.

Reckless Disregard - To act in "reckless disregard" means that the provider pays no regard to whether the information on a claim submitted for payment is true or false. An example of a provider who submits a false claim with reckless disregard would be a physician who assigns the billing function to an untrained office person without inquiring whether the employee has the requisite knowledge and training to accurately file such claims.

Penalty for Unlawful Conduct

The penalty for violating the False Claims Act is a minimum of \$5,500 up to a maximum of \$11,000 for each false claim submitted. In addition to the penalty, a provider could be found liable for up to three times the amount unlawfully claimed.

Examples

- A physician submitted claims to Medicare and Medicaid representing that he had personally performed certain services when, in reality, the services were performed by a nonphysician and they were not reimbursable under the Federal health care programs.
- Dr. X intentionally upcoded office visits and angioplasty consultations that were submitted for payment to Medicare.
- Dr. X, a podiatrist, knowingly submitted claims to the Medicare and Medicaid programs for non-routine surgical procedures when he actually performed routine, non-covered services such as the cutting and trimming of toenails and the removal of corns and calluses.

II. Civil Monetary Penalties Law (42 U.S.C. 1320a-7a)

Description of Unlawful Conduct

The Civil Monetary Penalties Law (CMPL) is a comprehensive statute that covers an array of fraudulent and abusive activities and is very similar to the False Claims Act. For instance, the CMPL prohibits a health care provider from presenting, or causing to be presented, claims for services that the provider "knows or should know" were:

APPENDIX E: CIVIL AND ADMINISTRATIVE STATUTES (continued)

- _ not provided as indicated by the coding on the claim;
- _ not medically necessary;
- _ furnished by a person who is not licensed as a physician (or who was not properly supervised by a licensed physician);
- _ furnished by a licensed physician who obtained his or her license through misrepresentation of a material fact (such as cheating on a licensing exam);
- _ furnished by a physician who was not certified in the medical specialty that he or she claimed to be certified in; or
- _ furnished by a physician who was excluded from participation in the Federal health care program to which the claim was submitted.

Additionally, the CMPL contains various other prohibitions, including:

- _ offering remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary to obtain items or services billed to Medicare or Medicaid from a particular provider; and
- _ employing or contracting with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program.

The term "should know" means that a provider: 1) acted in deliberate ignorance of the truth or falsity of the information; or 2) acted in reckless disregard of the truth or falsity of the information. The Federal Government does not have to show that a provider specifically intended to defraud a Federal health care program in order to prove a provider violated the statute.

Penalty for Unlawful Conduct

Violation of the CMPL may result in a penalty of up to \$10,000 per item or service and up to three times the amount unlawfully claimed. In addition, the provider may be excluded from participation in Federal health care programs. The regulations defining the aggravating and mitigating circumstances that must be reviewed by the OIG in making an exclusion determination are set forth in 42 CFR Part 1001.

Examples

1. Dr. X paid Medicare and Medicaid beneficiaries \$20 each time they visited him to receive services and have tests performed that were not preventive care services and tests.

APPENDIX E: CIVIL AND ADMINISTRATIVE STATUTES (continued)

2. Dr. X hired Physician Assistant P to provide services to Medicare and Medicaid beneficiaries without conducting a background check on P. Had Dr. X performed a background check by reviewing the HHS-OIG List of Excluded Individuals/Entities, Dr. X. would have discovered that he should not hire P because P is excluded from participation in Federal health care programs for a period of five years.
3. Dr. X and his oximetry company billed Medicare for pulse oximetry that they knew they did not perform and services that had been intentionally upcoded.

III. Limitations on Certain Physician Referrals ("Stark Laws") (42 U.S.C. 1395nn)

Description of Unlawful Conduct

Physicians (and immediate family members) who have an ownership, investment or compensation relationship with an entity providing "designated health services" are prohibited from referring patients for these services where payment may be made by a Federal health care program unless a statutory or regulatory exception applies. An entity providing a designated health service is prohibited from billing for the provision of a service that was provided based on a prohibited referral. Designated health services include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

New regulations clarifying the exceptions to the Stark Laws are expected to be issued by HCFA shortly. Current exceptions articulated within the Stark Laws include the following, provided all conditions of each exception as set forth in the statute and regulations are satisfied.

Exceptions for Ownership or Compensation Arrangements

1. physician's services;
2. in-office ancillary services; and
3. prepaid plans

Exceptions for Ownership or Investment in Publicly Traded Securities and Mutual Funds

1. ownership of investment securities which may be purchased on terms generally available to the public;
2. ownership of shares in a regulated investment company as defined by Federal law, if such company had, at the end of the company's most recent fiscal year, or on average, during the previous three fiscal years, total assets exceeding \$75,000,000;

APPENDIX E: CIVIL AND ADMINISTRATIVE STATUTES (continued)

3. hospital in Puerto Rico;
4. rural provider; and
5. hospital ownership (whole hospital exception).

Exceptions Relating to Other Compensation Arrangements

1. rental of office space and rental of equipment;
2. bona fide employment relationship;
3. personal service arrangement;
4. remuneration unrelated to the provision of designated health services;
5. physician recruitment;
6. isolated transactions;
7. certain group practice arrangements with a hospital (pre-1989); and
8. payments by a physician for items and services

Penalty for Unlawful Conduct

Violations of the statute subject the billing entity to denial of payment for the designated health services, refund of amounts collected from improperly submitted claims, and a civil monetary penalty of up to \$15,000 for each improper claim submitted. Physicians who violate the statute may also be subject to additional fines per prohibited referral. In addition, providers that enter into an arrangement that they know or should know circumvents the referral restriction law may be subject to a civil monetary penalty of up to \$100,000 per arrangement.

Examples

1. Dr. A worked in a medical clinic located in a major city. She also owned a free standing laboratory located in a major city. Dr. A referred all orders for laboratory tests on her patients to the laboratory she owned.
2. Dr. X agreed to serve as the Medical Director of Home Health Agency, HHA, for which he was paid a sum substantially above the fair market value for his services. In return, Dr. X routinely referred his Medicare and Medicaid patients to HHA for home health services.
3. Dr. Y received a monthly stipend of \$500 from a local hospital to assist him in meeting practice expenses. Dr. Y performed no specific service for the stipend and had no obligation to repay the hospital. Dr. Y referred patients to the hospital for in-patient surgery.

APPENDIX E: CIVIL AND ADMINISTRATIVE STATUTES (continued)

IV. Exclusion of Certain Individuals and Entities From Participation in Medicare and other Federal Health Care Programs (42 U.S.C. § 1320a-7)

Mandatory Exclusion

Individuals or entities convicted of the following conduct must be excluded from participation in Medicare and Medicaid for a minimum of five years:

- a criminal offense related to the delivery of an item or service under Medicare or Medicaid;
- a conviction under Federal or State law of a criminal offense relating to the neglect or abuse of a patient;
- a conviction under Federal or State law of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct against a health care program financed by any Federal, State, or local government agency; or
- a conviction under Federal or State law of a felony relating to unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

If there is one prior conviction, the exclusion will be for ten years. If there are two prior convictions, the exclusion will be permanent.

Permissive Exclusion

Individuals or entities convicted of the following offenses, may be excluded from participation in Federal health care programs for a minimum of 3 years:

- a criminal offense related to the delivery of an item or service under Medicare or Medicaid;
- a misdemeanor related to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct against a health care program financed by any Federal, State, or local government agency;
- interference with, or obstruction of, any investigation into certain criminal offenses;
- a misdemeanor related to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance;
- exclusion or suspension under a Federal or State health care program;
- submission of claims for excessive charges, unnecessary services or services that were of a quality that fails to meet professionally recognized standards of health care;

APPENDIX E: CIVIL AND ADMINISTRATIVE STATUTES (continued)

- violating the civil monetary penalties law or the statute entitled "Criminal Penalties for Acts Involving Federal Health Care Programs";
- ownership or control of an entity by a sanctioned individual or immediate family member (spouse, natural or adoptive parent, child, sibling, stepparent, stepchild, stepbrother or stepsister, in-laws, grandparent and grandchild);
- failure to disclose information required by law;
- failure to supply claims payment information; and
- defaulting on health education loan or scholarship obligations.

The above list is not all inclusive. Additional grounds for permissive exclusion are detailed in the statute.

Examples

1. Nurse R was excluded based on a conviction involving obtaining dangerous drugs by forgery. She also altered prescriptions that were given for her own health problems before she presented them to the pharmacist to be filled.
2. Practice T was excluded due to its affiliation with its excluded owner. The practice owner, excluded from participation in the Federal health care programs for soliciting and receiving illegal kickbacks, was still participating in the day-to-day operations of the practice after his exclusion was effective.

APPENDIX F: CARRIER CONTACT INFORMATION

Medicare

A complete list of contact information (address, phone number, email address) for Medicare Part A Fiscal Intermediaries, Medicare Part B Carriers, Regional Home Health Intermediaries, and Durable Medical Equipment Regional Carriers can be found on the HCFA website at www.hcfa.gov/medicare/incardir.htm.

Medicaid

Contact information (address, phone number, email address) for each state Medicaid carrier can be found on the HCFA website at www.hcfa.gov/medicaid/mcontact.htm. In addition to a list of Medicaid carriers, the website includes contact information for each State survey agency and the HCFA Regional Offices.

APPENDIX G: INTERNET RESOURCES

Office of Inspector General - U.S. Department of Health and Human Services (www.hhs.gov/oig)

This website includes a variety of information relating to Federal health care programs, including the following:

Advisory Opinions
Anti-Kickback Information
Compliance Program Guidance
Corporate Integrity Agreements
Fraud Alerts
Links to web pages for the:
Office of Audit Services (OAS)
Office of Evaluation and Inspections (OEI)
Office of Investigations (OI)
OIG List of Excluded Individuals/Entities
OIG News
OIG Regulations
OIG Semi-Annual Report
OIG Workplan

Health Care Financing Administration (www.hcfa.gov)

This website includes information on a wide array of topics, including the following:

Medicare

National Correct Coding Initiative
Intermediary-Carrier Directory
Payment Program
Manuals
Program Transmittals & Memorandum
Provider Billing/HCFA Forms
Statistics and Data

Medicaid

HCFA Regional Offices
Letters to State Medicaid Directors
Medicaid Hotline Numbers
Policy & Program Information
State Medicaid Contacts
State Medicaid Manual
State Survey
Agencies
Statistics and Data

APPENDIX G: INTERNET RESOURCES (continued)

HCFA Medicare Training (www.medicaretraining.com)

This site provides computer-based training on the following topics: HCFA 1500 Form Fraud & Abuse ICD-9-CM Diagnosis Coding Adult Immunization Medicare Secondary Payer (MSP) Women's Health Front Office Management Introduction to the World of Medicare Home Health Agency HCFA 1450 (UB92)