


FRAUD AND ABUSE COMPLIANCE
IMPLEMENTING A COMPLIANCE PLAN (2003)

Massachusetts Medical Society

The information contained in this manual is intended to serve as a general resource and guide. It is not to be construed as legal advice. Attorneys with knowledge of the fraud and abuse laws should be consulted regarding the application of these laws to specific situations.

This manual was prepared by Paul Shaw, Esq. of the law firm of Brown, Rudnick, Berlack Israels LLP in conjunction with the Massachusetts Medical Society's Office of the General Counsel and under the direction of the Massachusetts Medical Society's Department of Health Policy/Health Systems.

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INTRODUCTION

Medicare and Medicaid fraud and abuse continues to remain a top priority for the government. In light of the seriousness of fraud and abuse offenses, ongoing enforcement activity, and associated criminal and civil penalties, physicians need to continue their compliance efforts to ensure that they are abiding by all relevant state and federal laws governing fraud and abuse-related violations. The Department of Health and Human Services and the Department of Justice Health Care Fraud and Abuse Control Program Annual Report Fiscal Year 2001 detailed the following statistics:

MONETARY RESULTS IN 2001. The Federal government won or negotiated more than \$1.7 billion in judgments, settlements, and administrative impositions in health care fraud cases and proceedings. As a result of these activities, as well as prior year judgments, settlements, and administrative impositions, the Federal government collected more than \$1.3 billion. More than \$1 billion of the funds collected and disbursed in 2001 were returned to the Medicare Trust Fund. An additional \$42.8 million was recovered as the Federal share of Medicaid restitution. This is the largest return to the government since the inception of the Program.

ENFORCEMENT ACTIONS. Federal prosecutors filed 445 criminal indictments in health care fraud cases in 2001. A total of 465 defendants were convicted for health care fraud-related crimes in 2001. There were also 1,746 civil matters pending and 188 civil cases filed in 2001. HHS excluded 3,756 individuals and entities from participating in the Medicare and Medicaid programs, or other federally sponsored health care programs, most as a result of licensure revocations. This record number of exclusion actions is the result of successful collaboration with state Medicaid Fraud Control Units (MFCUs) and state licensure boards.

The federal government through its Office of Inspector General (OIG) has taken a pledge to continue working with the provider community and to promote the adoption of voluntary compliance programs, including issuing compliance program guidance, special fraud alerts, and advisory opinions. The ongoing efforts undertaken by the provider community at-large to comply with the government's fraud and abuse laws and regulations have been duly recognized by the Inspector General in her recent statement, which noted the following:

As we move into our next reporting period, I thank those many providers who have worked willingly with us to build a stronger relationship and to seek ways to eliminate fraud and abuse. As a result of our collaborative efforts, I feel confident that we will find increasing success in meeting the ever-changing, increasingly complex needs of our beneficiaries.

The Massachusetts Medical Society (MMS) has put together this booklet in an attempt to assist physicians with their ongoing compliance efforts. The information contained within these pages is not intended to meet individual physician's needs but rather to serve as a general reference and educational guide. Physicians are encouraged to seek advice from their own counsel to address specific legal issues that arise in their individual practices.

Other MMS Resources

The MMS has developed a comprehensive strategy to help physicians cope with the ongoing demands of Medicare and Medicaid compliance:

EDUCATION. The MMS provides seminars on a variety of topics, including Medicare documentation requirements, coding and billing, and medical record audits. The MMS also offers seminars that provide step-by-step instructions for implementing a compliance plan in the medical office and how to respond to an investigation. Contact the MMS Medical Education Department for information on upcoming programs.

PERSONALIZED ASSISTANCE. The MMS will provide reimbursement assistance in response to questions over the phone.

RESOURCE KITS. The MMS provides informational materials on physician compliance and other major topics affecting physician practices.

ATTORNEY AND PRACTICE MANAGEMENT CONSULTING. The MMS has available a full spectrum of credentialed consultants who can assist you in coding, billing, and compliance issues.

To find out more about these and other MMS services, contact the Physician Practice Resource Center at pprc@massmed.org or the Department of Health Policy/Health Systems at (781) 434-7222.

CHAPTER 1 ~ Overview

Responding to the OIG's Final Compliance Guidance for Individual and Small Group Physician Practices

On September 25, 2000, the Office of Inspector General (OIG) issued final Compliance Program Guidance for Individual and Small Group Physician Practices. (The document can be found on the OIG's website at www.oig.hhs.gov/authorities/docs/physician.pdf.) This document contains a detailed outline of how the OIG believes individual and small group physician practices should approach compliance.

Unlike past compliance guidance for hospitals, clinical laboratories, third-party billing companies, and other institutional providers, where the OIG rigidly recommends implementing seven standard compliance plan elements, in the Compliance Program Guidance for Individual and Small Group Physician Practices, the OIG takes a more flexible approach and recognizes the administrative and financial constraints facing physician practices. Specifically, this guidance sets out a step-by-step process designed to allow physicians to pick and choose which of these seven elements can be implemented efficiently. The OIG notes that “[it is] encouraging physician practices to adopt the active application of compliance principles in their practice, rather than implement rigid, costly, formal procedures. [The OIG's] goal in issuing this final guidance was to show physician practices that compliance can become a part of the practice culture without the practice having to expend substantial monetary or time resources.”

The flexible nature of this guidance allows physicians to engage in significant compliance efforts with a limited amount of burden. In this era of high government scrutiny, where fraud investigations and post-payment audits are commonplace, it behooves even individual and small group practices to develop some form of a compliance program. In the context of a physician practice, a compliance program is basically a set of principles and protocols focused on insuring the practice's compliance with applicable laws and regulations. When facing an investigation, the ability to show a good-faith effort to control, monitor, and eliminate billing errors can significantly benefit the practice in its relations and negotiations with government representatives.

It is recommended, therefore, that physician practices attempt to follow the OIG's step-by-step process and develop a compliance plan tailored to meet the needs of the practice. At the same time, it must be emphasized that these compliance guidelines are entirely voluntary. The key should be that whatever approach is undertaken, in the event of an audit or investigation, the practice must be able to demonstrate the efforts it took to monitor compliance.

Step-by-Step Approach

The OIG's compliance guidance prioritizes which steps a small physician practice should take when developing a compliance program. Importantly, the OIG attempts to maximize the benefit physicians receive from compliance plans by indicating that as a first step “physician practices can begin by adopting only those components which, based on a practice's specific history with billing problems and other compliance issues, are most likely to provide an identifiable benefit.” The OIG recognizes that some practices “may never fully implement all of the [seven] components.” Instead, each practice should develop a compliance program that is workable and reflective of the individual practice. Irrespective of whatever procedures and protocols are adopted by a practice, the most important element of an effective compliance program is commitment by the physician members of the practice.

The following provides a brief summary of the OIG's guidelines regarding the seven elements of a compliance plan.

Step 1: Auditing and Monitoring

If a practice is to benefit from a compliance program, it must address the specific risk areas and issues relevant to that practice. Consequently, the crucial first step to implementing a compliance program is the review/maintenance of a practice's policies and standards and the identification of the practice's risk areas. The OIG recommends that practice policies and standards be updated periodically to ensure they are current in light of changes to federal laws and regulations, as well as to CPT and ICD-9 codes. The OIG also suggests reviewing its current work plan and semiannual reports to identify additional risk areas. Each year, the work plan identifies areas of physician practices that will be the focus of OIG investigations. These documents are available on the OIG's website at www.oig.hhs.gov/publications.html. In the Fiscal Year 2002 work plan, for example, the following are some of the issues that will be reviewed: advance beneficiary notices, Evaluation and Management (E&M) coding, consultations, services and supplies furnished incident to physicians' services, reassignment of benefits, bone-density screening, and physicians at teaching hospitals.

Additionally, the OIG suggests that each practice identify any "risk areas" affecting the practice's medical records and billing practices. The following are four potential risk areas that affect most physician practices:

- Improper coding and billing
- Ensuring that services are reasonable and necessary
- Proper documentation
- Avoiding improper inducements, kickbacks, and self-referrals

An appendix to the final guidance identifies other risk areas that should be reviewed when implementing a compliance program. These include issues relating to the reasonable and necessary services, a variety of physician billing practices, and physician relationships with hospitals.

CONDUCTING A BASELINE AUDIT. Each of these risk areas should be considered when performing an internal review. Thereafter, the practice will need to conduct a review of a sample of records to establish a benchmark about its current level of compliance with the documentation and billing regulations. This review can be a self-audit performed by the practice's billing and medical staff or by an outside reviewer. The review can be done either retrospectively or concurrently with the claims submission. The OIG recommends that the practice review five or more medical records for each federal program (Medicare, Medicaid, CHAMPUS, etc.) the practice participates in or 5 to 10 records per physician. This should be the minimum number of records reviewed, as the larger the sample size the greater the comfort level the practice will have with the results of its internal audit. Following this baseline review, the OIG recommends the practice conduct periodic audits at least once a year to insure that the compliance program is being followed. If the baseline audit or subsequent audit reveals problems or overpayments, the practice should repay any overpayments and engage in focused reviews and monitoring of the detected problem areas.

Finally, as part of its initial compliance review, the practice should review all its contracts with vendors and others to insure the arrangements comply with the Anti-Kickback law and the "Stark" law regarding physician self-referrals.

Step 2: Establishing Written Policies and Procedures

Written standards and procedures act as a central component to any compliance plan. These standards should include an identification of the practice's risk areas and procedures for the staff to follow when incidents occur. It is critical that a small group practice implementing a compliance plan document its policies and make them available to staff. It is especially important that the responsibilities and expectations of employees be

incorporated into the code of conduct. The OIG recommends creating a compliance resource manual that contains not only the practice's written standards and procedures but also relevant Medicare directives and carrier bulletins, as well as summaries of OIG Special Fraud Alerts and advisory opinions.

Step 3: Appointing a Compliance Officer

Following the completion of an internal audit and the development of policies, a practice should appoint one or more staff members to serve as "compliance officers" to monitor compliance activity and develop corrective action plans when necessary. For small practices, the OIG suggests that compliance officer responsibilities can be divided among several staff members who will act as contacts with regard to particular areas. For example, one staff member (such as the office manager) may be assigned the role of drafting and maintaining written policies, while another (such as the billing supervisor) may be responsible for conducting periodic audits.

However, one person, preferably a physician member of the practice, should have overall responsibility for the compliance program. It is critical for the successful operation of any compliance program that whoever is assigned or chosen for this task should be approachable by the staff. The responsibilities of the compliance officer for a small practice are outlined in Chapter 4.

Additionally, the OIG indicates that it may be appropriate for a practice to outsource compliance officer responsibilities. If a practice chooses to hire an outside individual or entity to take on the compliance officer role, it is important that the individual or entity maintain a working relationship and familiarity with the practice.

Step 4: Training and Education

Following the appointment of a compliance officer, a training strategy should be developed that will allow staff to become familiar with the practice's risk areas, policies, and procedures. The goal of training and education is to ensure that practice staff is educated and aware of the rules and regulations governing the practice's business, as well as the particular risk areas to avoid and monitor. The OIG notes that the extent and level of education and training will differ depending upon the needs and size of each practice.

Education and training sessions should generally address two areas: (1) compliance training for all staff and (2) coding and billing training for individuals involved in the practice's claims procedures. Compliance training should include training on the operation and importance of the compliance program, the consequences of violating the standards and procedures, and the role of each employee in the operation of the compliance program. The OIG suggests that coding and billing training cover the following: coding requirements, claim development and submission processes, the signing of physician forms without physician authorization, proper billing and documentation of services, the ramifications of altering medical records, and the legal sanctions for fraudulent billing.

The OIG's guidance is flexible as to how training of employees should be conducted. Training and educational activities can be as formal as holding on-site or off-site seminars regarding practice policies or coding techniques or as informal as distributing or posting educational materials and compliance policies on easily accessible bulletin boards. One excellent method of training staff regarding fraud and abuse is through a computer/Web-based training program. Such programs can be found through the Medicare Learning Network at www.hcfa.gov/medlearn. The OIG's final guidance contains appendices that outline the various risk areas affecting physician practices, as well as information about criminal, civil, and administrative statutes relating to federal health care programs. According to the OIG, these appendices can serve as a resource when developing training and education programs.

Finally, compliance training must be conducted on a continuing basis. The OIG recommends that there be at least annual training of all individuals involved in the coding and billing aspects of the practice.

Step 5: Responding to Detected Offenses and Developing Corrective Action Initiatives

A practice must respond to indications of compliance violations. If a violation or an overpayment is alleged or discovered, the compliance officer should conduct an investigation to determine the nature and scope of the potential problem. Depending upon the issue discovered, it may be appropriate for a corrective action plan to be created, for overpayments to be returned, or, in some cases, for the practice to make a voluntary disclosure to the government. Although the voluntary disclosure of an overpayment or abusive conduct does not prevent the OIG from bringing an enforcement action or the U.S. Attorney from initiating a civil or criminal proceeding, both the OIG and the Department of Justice consider the act of voluntary disclosure to be a mitigating factor in determining whether to bring such an action.

The critical aspect of this component is that the practice take steps to address the violations it discovers. The OIG stresses that “if the physician practice ignores reports of possible fraudulent activity, it is undermining the very purpose it hoped to achieve by implementing a compliance program.” The OIG also indicates that practices should document the reporting of noncompliant conduct and any follow-up action.

No matter what the nature of the violation or how it was discovered, it is critical that a practice engage in corrective measures with whatever staff members (including physicians) who were involved in the violation. This can range from an educational meeting or sending the employee for training to reprimand or termination, depending on the nature of the violation and the employee’s culpability. Whatever is done, it is important that corrective actions be thoroughly documented.

Step 6: Developing Open Lines of Communication

An open line of communication between staff and the management of a practice is critical to the successful operation of a compliance program. Providing staff with an easy mechanism for reporting potential problems or violations allows the practice to address and eliminate compliance issues before they escalate. In its other guidance, the OIG recommends the use of telephone hotlines or e-mail systems to allow anonymous reporting. With regard to smaller physician practices, the OIG recognizes the cost-prohibitive nature of such systems and suggests the use of “open door” policies, bulletin boards, and other such low-cost methodologies — an anonymous “drop box” for complaints or concerns, for instance. Primarily, the OIG emphasizes the importance of creating an environment where staff members are encouraged to report potential issues without fear of retribution for doing so.

Step 7: Enforcing Disciplinary Standards through Use of Well-Publicized Guidelines

The OIG’s final recommendation to individual and small group physician practices is that staff members be made aware of the consequences resulting from acting in a noncompliant manner. The OIG indicates that effective compliance programs have procedures for dealing with individuals who violate the practice’s policies or compliance standards and that such procedures are well publicized (i.e., included in training manuals). Disciplinary action should also be imposed against any employee who fails to reasonably detect or report violations of the compliance program. A practice should use consistent and appropriate sanctions while, at the same time, taking into account both mitigating and aggravating circumstances. Finally, as stated above, disciplinary action can range from written warnings and reprimands to suspension and/or discharge. As with every other component of the compliance program, all disciplinary actions should be documented.

As stated above, while adoption of the OIG's compliance guidance by physicians is entirely voluntary, it is important for every physician practice, no matter how small, to implement some aspects of a compliance program. The OIG's guidance for physician practices is flexible and allows every practice to implement certain elements of a compliance program with minimal disruption to the practice's operations.

There is no set-in-stone number of physicians that makes a practice too large to follow this guidance. What is important, however, is that a larger group practice attempt to implement as many components as possible. Practices should remember that the ultimate goal in developing a compliance plan is to make a good faith effort to monitor and prevent fraud, abuse, and billing errors. If a large practice takes minimal preventative steps, it is unlikely to be viewed by investigators as being effective at ensuring compliance. The OIG notes within its guidance that larger practice groups may choose to incorporate elements of the OIG's guidance for other entities they regularly do business with (e.g., third-party medical billing company compliance guidance).

Conversely, it is important for even an individual practitioner to implement some form of compliance program. Individual practitioners face many of the same billing issues, staff issues, and risk areas that are faced by larger groups. An individual practitioner should identify potential risk areas and develop and document policies and standards addressing these areas. An individual practitioner can greatly benefit from the flexible nature of this guidance, such as using bulletin boards and open-door policies. Individual practitioners should take advantage of the small and personal nature of their practices by paying close attention to staff concerns and billing issues.

All compliance plans should evolve as time passes. As new regulations are promulgated and as new OIG fraud alerts are issued, practices should reevaluate their compliance plans to ensure that they effectively address any risk areas. Moreover, a compliance plan should evolve to address the changing nature of the practice for which it was originally formed.

CHAPTER 2 ~ Summary of Fraud and Abuse Laws

There are a number of overlapping federal and state statutes relating to health care fraud and abuse. From a physician's perspective, the following is a summary of the criminal, civil, and administrative statutes most commonly used to prosecute and sanction health care fraud and abuse.

Federal Criminal Statutes

There are a myriad of federal criminal statutes used by the federal government to prosecute health care fraud. Some of the most common include the following:

Health Care Fraud (18 U.S.C. § 1347)

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 a false representation. This law applies not only to federal health care programs but to most other types of health care benefit programs, such as commercial health insurance plans.

Examples of conduct that frequently give rise to liability include the following:

- Billing for services never provided to patients.
- “Upcoding”: billing for more extensive services than were actually rendered.
- Falsely certifying that services were medically necessary.
Note: On every HCFA 1500 claim form, a physician must certify that the services rendered were medically necessary for the health of the beneficiary.
- “Unbundling”: billing for each component of the service instead of billing an all-inclusive code.
- Billing for non-covered services as if covered.
- Flagrant and persistent overutilization of medical services with little or no regard for results, the patient's ailments, condition, or medical needs.
- Consistent use of improper or inappropriate billing codes, such as billing for the same level of service or diagnosis code irrespective of the services rendered in the individual case.

The following are three examples of health care fraud provided by the federal Office of Inspector General (OIG):

- A physician intentionally billed Medicare for treatments that he never actually rendered for the purpose of fraudulently obtaining Medicare payments.
- A psychiatrist billed Medicare, Medicaid, TRICARE, and private insurers for psychiatric services that were provided by his nurses rather than himself.
- A physician intentionally upcoded the level of E&M service rendered to patients to increase Medicare payments.

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

It is a crime to knowingly and willfully falsify or conceal a material fact, make any materially false statement, or use any materially false, fictitious, or fraudulent writing or document in connection with the delivery of or payment for health care benefits, items, or services.

An example would be a physician who 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.

Theft and Embezzlement Relating to Health Care Benefit (18 U.S.C. § 669)

It is a crime to knowingly and willfully embezzle, steal, or intentionally misapply any assets of a health care benefit program.

An example of conduct punishable under this statute would be an office manager for a physician who knowingly embezzles money from the practice's bank account that includes reimbursement received from the Medicare program.

False Claims Act (18 U.S.C. § 287)

The False Claims Act is one of the primary tools used by the federal government to prosecute fraudulent billing practices under Medicare and Medicaid. The statute prohibits the presenting of a claim to the United States that the claimant knows to be "false, fictitious, or fraudulent."

The range of conduct punishable under the False Claims Act is extremely broad and includes

- Billing for services that were not rendered;
- Filing claims for services billed at inflated rates; and/or
- Filing for services that were not medically necessary.

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

As correspondence with Medicare and Medicaid generally involves the use of the mails and electronic wiring systems, parties engaged in submitting false claims to the government frequently fall subject to prosecution under the mail and wire fraud statutes. Specifically, government programs and private providers invariably utilize the mails to send or receive payments, explanation of benefit forms, and other related documents. Similarly, providers often submit claims to the government through electronic wire systems. Consequently, these two statutes, which prohibit the use of the mails or the wires to further "schemes" to defraud, are often applied against parties submitting false claims. The mail and wire fraud statutes cover the entire range of fraudulent conduct punishable under the Health Care Fraud and False Claims Acts.

Examples provided by the OIG include the following:

- A physician 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.
- A neurologist knowingly submitted claims for tests that were not reasonable and necessary and intentionally upcoded office visits and electromyograms to Medicare.

Medicare and Medicaid Patient Protection Act of 1987 (42 U.S.C. § 1320a-7b(a))

This statute proscribes six specific types of conduct, including the making of false statements, the concealment of information with intent to induce improper payments, improperly converting federal payments, and submitting claims for services provided by unlicensed individuals.

This section's most commonly enforced provision prohibits individuals from "knowingly and willfully mak[ing] or caus[ing] to be made any false statement or representation of a material fact in any application for any benefit

or payment under [the Medicare or Medicaid programs].” As claims containing any false statements regarding material facts are actionable under this provision, many activities beyond the blatant billing for unrendered services may lead to violations.

Examples of other prohibited conduct under this provision include

- Misrepresenting services actually rendered (e.g., upcoding) and
- Falsely certifying that certain services were medically necessary.

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

This statute is frequently used during a health care fraud investigation by the government. The statute prohibits the obstruction of a criminal investigation in any material way, such as by failing to produce subpoenaed records, destroying or altering records, or attempting to influence the testimony of an employee questioned by government investigators.

Examples include the following:

- A physician instructs his employees to tell OIG investigators that he personally performs all treatments when, in fact, medical technicians do the majority of the treatment and the doctor is rarely present in the office.
- A physician under investigation by the FBI for reported fraudulent billings alters his patient records in an attempt to cover up the improprieties.
- A physician intentionally fails to produce certain records during an investigation because they could incriminate him.

Anti-Kickback Statute (42 U.S.C. §1320a-7(b))

The federal Anti-Kickback Statute provides criminal and civil penalties for certain business arrangements that are influenced by the referral of patients for health care services covered by a federal health care program, such as Medicare and Medicaid. Specifically, the anti-kickback law prohibits the following:

The knowing and willful solicitation, receipt, offer, or payment of any remuneration (which includes payments and anything else of value) whether direct or indirect, overt or covert, in cash or in kind, in return for

- Referring an individual for any item or service covered by a federal health care program or
- Purchasing, leasing, ordering or arranging for, or recommending or arranging for the purchase, lease, or ordering of any item of service paid for (in whole or in part) under a federal health care program.

The general purpose of this statute is to prohibit anyone from paying or accepting a payment in exchange for referring a patient for services that might be covered by the Medicare and Medicaid programs. What this means is that a physician cannot give gifts or anything of value in order to induce referrals of patients to his or her practice. Furthermore, the opposite is also true: A physician cannot accept gifts or things of value from a vendor, such as a medical laboratory, in order to do business with that vendor. Examples: cash, vacations, gift certificates, etc.

Of interest to physicians is the fact that many standard recruitment incentives offered by hospitals to physicians may constitute illegal remuneration. In 1992, the OIG issued a Special Fraud Alert identifying numerous physician incentives as suspect. The theory underlying the OIG's alert is that these discounts and incentives are,

in fact, payments for the referral of Medicare-paying patients to the hospital. The list of suspected incentives includes

- Free or discounted office space or equipment;
- Free or discounted billing, nursing, or other staff services;
- Free training for a physician's office staff;
- Income guarantees;
- Low-interest or interest-free loans, including "forgiven" loans;
- Payments for physician services that involve few substantive duties or exceed fair market value; and/or
- Payment for physician continuing medical education courses, or travel and expense payments to attend conferences.

The following are other examples of conduct that violate the Anti-Kickback Statute:

- Routinely waiving co-payments or deductibles for patients without determining if the patient has financial hardship.
- Accepting payments to sign Certificates of Medical Necessity for durable medical equipment for patients never examined.
- A home health agency disguises referral fees as salaries by paying a physician for services either never rendered or in excess of fair market value for the services rendered.
- Payment by a hospital or other facility to a physician for each patient the hospital or facility admits.
- Payment by a hospital for medical director services in excess of fair market value.

SAFE HARBOR REGULATIONS. Because the literal wording of the Anti-Kickback Statute prohibits a number of transactions generally believed to be necessary or beneficial to the health care industry, Congress authorized the creation of a number of "safe harbors" that permit conduct prohibited under this act. The following are some of the items that are covered by the Safe Harbor Regulations:

- Payments reflecting returns on investment in connection with investments in certain business entities;
- Payments made in connection with space or equipment rental arrangements;
- Personal services and management contracts (e.g., medical director contracts or other independent contractor arrangements);
- Sale of a physician practice;
- Referral services;
- Practitioner recruitment;
- Ambulatory surgical centers; and
- Referral agreements for specialty services.

A physician entering into an arrangement involving any of the above practices, or where there is the potential for the referral of patients for services, should consult with a competent health care attorney.

STATE ANTI-KICKBACK LAW. Massachusetts also has an anti-kickback statute that is similar to the federal statute with one major exception: The state statute has no “intent” requirement.

Perjury and False Statements

These two general criminal statutes are also used in connection with health care fraud investigations.

PERJURY BY WRITTEN INSTRUMENT. All Medicare and Medicaid claim forms have a written certification that the statements made in connection with the claim are submitted under the penalties of perjury.

FALSE STATEMENTS (18 U.S.C. § 1001). Another federal criminal statute frequently used to prosecute health care fraud is the provision relating to false statements. This statute prohibits the making of any false, fictitious, or fraudulent statement to the United States or a government agency. This statute is exceedingly broad: It covers any statement or representation made to the government or any of its agents. A statement can be made either orally or in writing, and it can be sworn or unsworn. This statute is often used to prosecute witnesses or others who lie to FBI agents during the course of an investigation.

Massachusetts Criminal Statutes

Massachusetts has a number of criminal and civil statutes that are used to prosecute health care fraud and abuse violations.

THE MASSACHUSETTS MEDICAID FALSE CLAIMS ACT (M.G.L. c. 118E, § 21A ET SEQ.). In 1980, Massachusetts enacted a comprehensive Medicaid False Claims Act that covers a number of prohibited activities, including fraudulent billing to the Medicaid program and anti-kickback provisions. The statute authorizes state prosecutors to bring criminal or civil action against any person violating the statutory provisions of the Massachusetts Medical Assistance (Medicaid) Program. In addition to criminal penalties, the Act provides for civil penalties of treble damages and the cost of the government investigation and litigation.

FALSE REPRESENTATIONS TO SECURE MEDICAID PAYMENT. This statute prohibits providers from knowingly making false representations to secure payment from Medicaid.

MASSACHUSETTS FALSE HEALTH CARE CLAIMS ACT (M.G.L. c. 175H, §§2-4). The False Health Care Claims Act prohibits the submission of fraudulent bills to private health insurers and other health care organizations. Additionally, the statute prohibits the solicitation or receipt or any “bribe or rebate” in connection with a private health care entity. Apart from criminal prosecution, the health insurer is authorized to bring a civil action to recover the full amount inappropriately paid, together with attorneys’ fees and the costs of investigation.

OTHER STATE STATUTES. The Massachusetts General Laws contain a number of general criminal statutes that are used in health care fraud and abuse prosecutions. Prosecutors frequently charge individuals suspected of health care fraud and abuse with larceny and the making of false statements in a statement verified under penalties of perjury.

Civil and Administrative Statutes

Federal False Claims Act

The civil False Claims Act (FCA) is the law most often used to bring a civil case against a health care provider for the submission of false claims to a federal health care program, including the Medicare or Medicaid programs. As a result of its penalty provisions, the FCA represents one of the most powerful enforcement tools that the federal government has at its disposal in connection with health care fraud. Under the FCA, any person or entity knowingly making a false claim to the government (i.e., to Medicare) is liable for mandatory civil penalties and fines. Even the mere filing of a false claim that is never paid triggers liability under the FCA.

Each individual false claim submitted to Medicare/Medicaid gives rise to potential penalties between \$5,500 and \$11,000, coupled with treble damages for the amounts paid by the government. Consequently, each false “line item” claimed can result in thousands of dollars of liability. In cases where providers submit significant numbers of claims (e.g., hospitals or laboratories), total exposure to liability may amount to millions of dollars. Often, the government merely has to brandish the amount of potential liability under this Act to leverage settlements with providers who would be financially crippled if found guilty.

To establish liability under the FCA, the government must establish the following: (1) the provider presented or caused to be presented to an agent of the United States a claim for payment, (2) the claim was false or fraudulent, and (3) the defendant knew that the claim was false or fraudulent. Importantly, the knowledge requirement for liability under the civil FCA is lower than under the criminal statute. The civil FCA defines “knowing” and “knowingly” as either actual knowledge, deliberate ignorance, or the “reckless disregard of the truth or falsity of the information.”

As a result, a physician does not have to deliberately intend to defraud the government to be liable. Liability can be imposed on a provider who has deliberately or recklessly chosen to ignore the truth or falsity of the information on a claim submitted for payment, when the provider knows, or has noticed, that information may be false. An example of deliberate ignorance would be a physician who ignores provider update bulletins and thus does not inform his or her staff of changes in the Medicare billing guidelines or update his or her billing system in accordance with said changes. When claims for non-reimbursable services are submitted as a result, the False Claims Act has been violated. An example of 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.

At the same time, physicians are not subject to criminal, civil, or administrative penalties for innocent mistakes or errors, or even negligence. Specifically, the Department of Justice has stated that where billing errors, honest mistakes, or negligence result in improper claims the provider may be asked to return the funds, but without penalties. Indeed, the OIG in the Compliance Program Guidance for Individual and Small Physician Practices states as follows:

“Even ethical physicians (and their staffs) make billing mistakes and errors through inadvertence or negligence. When physicians discover that their billing errors, honest mistakes, or negligence result in erroneous claims, the physician practice should return the funds erroneously claimed, but without penalties. In other words, absent a violation of a civil, criminal, or administrative law, erroneous claims result only in the return of funds claimed in error.”

Here are some examples provided by the OIG of conduct that violates the False Claims Act:

- 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.
- A cardiologist intentionally upcoded office visits and angioplasty consultations that were submitted for payment to Medicare.
- 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.

Federal Physician Self-Referral Prohibitions

The Stark Law

The Stark prohibitions are designed to prevent physicians from making money from the patients they treat. The Stark laws prohibit a physician from referring a Medicare or Medicaid patient for “designated health services” in which the physician (or immediate family member) has an ownership or investment interest or compensation relationship. In practice, the prohibitions have caused grave uncertainty for physicians and providers of health care services as they struggle to respond to the market forces that have reshaped the health care industry over the past few years.

STARK I. The initial Stark Law, colloquially known as “Stark I,” prohibits a physician from referring a Medicare patient for testing to a clinical laboratory in which the physician (or an immediate family member) has a financial interest or relationship.

STARK II. In 1993, Congress enacted “Stark II.” This law expanded the referral and billing prohibitions to Medicaid, as well as added 10 additional “designated health services” as follows:

1. Physical therapy services;
2. Occupational therapy services;
3. Radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services;
4. Radiation therapy services and supplies;
5. Durable medical equipment (DME) and supplies;
6. Parenteral and enteral nutrients, equipment, and supplies;
7. Prosthetics, orthotics, and prosthetic devices;
8. Home health services and supplies;
9. Outpatient prescription drugs; and
10. Inpatient and outpatient hospital services.

For the purpose of the Stark laws, the term “referral” is defined as an item or service for which payment may be made by Medicare/Medicaid. In the event a patient obtains an item or service from an entity in which the

physician or family member has a financial relationship, the Stark Law is violated unless one of the statutory or regulatory exceptions apply. Examples of violations of the Stark Law include the following:

- A physician works in a medical clinic and also owns a free-standing laboratory located in the same city. The physician referred all orders for laboratory tests on her patients to the laboratory she owned.
- A doctor 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, he routinely referred his Medicare and Medicaid patients to HHA for home health services.
- A physician received a monthly stipend of \$500 from a local hospital to assist him in meeting practice expenses. The doctor performed no specific services for the stipend and had no obligation to repay the hospital. The doctor referred patients to the hospital for inpatient surgery.

Unlike the Anti-Kickback Statute, which is a statute separate and apart from the Stark Law, an intent to violate the Stark Law is not required for penalties to be imposed. Stark is entirely objective and a “zero tolerance” statute. Thus, knowledge of the scope and application of the Stark Law is crucial to avoid sanctions.

It is beyond the scope of this memorandum to discuss the Stark laws and the various statutory and regulatory exceptions in any detail. Our advice is simple: If a physician or an immediate family member has a financial interest in one of the “designated health services,” seek legal advice about the arrangement, as the penalties under the law are very severe. A physician can be subject to a civil monetary penalty of up to \$15,000 per claim for each prohibited service and exclusion from the Medicare and Medicaid programs.

Civil Sanctions Fines and Exclusions

There are additional, noncriminal sanctions that may result from criminal liability or may be separately imposed for nonconforming conduct. Generally, civil (noncriminal) sanctions include civil monetary penalties and/or exclusion from participation in the Medicare and Medicaid programs.

Civil money penalties can be imposed for violations of the fraud and abuse laws in addition to criminal penalties. Civil money penalties of up to \$10,000 per item or service, plus an assessment of up to three times the amount claimed for each such item or service, may be imposed upon any provider who knowingly presents or causes to be presented a claim for Medicare or Medicaid reimbursement that

- Is for an item or service that the person knows or should know was not provided as claimed;
- Is for an item or service and the person knows or should know the claim is false or fraudulent; and/or
- Is presented for a physician’s service by a person who knows or should know that the individual who furnished the service was not properly licensed as a physician or is a physician who falsely claimed to the patient that he or she is specialty certified by a medical specialty board.

Some examples of conduct that could result in the imposition of civil monetary penalties include the following:

- 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.
- Dr. X hired a physician assistant (PA) to provide services to Medicare and Medicaid beneficiaries without conducting a background check. Had Dr. X performed a background check by reviewing the HHS-OIG List of Excluded Individuals/Entities, he would have discovered that he should not hire the PA because the PA was excluded from participation in federal health care programs for a period of five years.
- Dr. X and his oximetry company billed Medicare for pulse oximetry services that he knew were not performed and for services that had been intentionally upcoded.

Exclusions can result from a conviction for health care fraud or other impermissible conduct. If a physician is excluded from the Medicare or Medicaid programs, it means that no Medicare or Medicaid payments will be made for any services rendered by that physician.

The Office of Inspector General has the authority to exclude physicians and other health care providers from the Medicare and Medicaid programs. There are two categories of exclusion: mandatory and permissive.

MANDATORY EXCLUSION. Individuals or entities convicted of any of the following crimes 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 criminal offense under federal or state law relating to the neglect or abuse of a patient in connection with the delivery of a health care item or service.
- A felony under federal or state law 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.
- A felony under federal or state law relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

PERMISSIVE EXCLUSION. There are a number of grounds for which the OIG has discretion to exclude a physician from the Medicare and Medicaid programs for a minimum of three years. The following list is not all-inclusive but are some of the most frequently used grounds for permissive exclusion:

- Misdemeanor convictions relating to health care fraud
- Convictions relating to fraud in non-health care programs
- Convictions for obstructing an investigation
- Misdemeanor convictions for controlled substance violations
- License revocations or suspensions
- Fraud, kickbacks, and other prohibited activities
- Submitting claims for unnecessary or substandard services
- Submitting false or improper claims
- Exclusion or suspension from any other federal or state health care program
- Defaulting on a health education loan or scholarship obligation
- Entities controlled by an individual who is subject to mandatory exclusion
- Failure to disclose required information
- Failure to grant immediate access to a fraud investigator
- Failure to take corrective action

State Administrative and Licensing Consequences

Physicians who have been convicted of larceny or fraud or any other crime in connection with the billing of the Medicaid program are not permitted to participate as Medicaid providers. The Division of Medical Assistance has

discretion to terminate or exclude physicians who work in a close professional association with providers convicted of a program-related offense.

Most professional licensing boards, including the Board of Registration in Medicine, are empowered to discipline licensees based solely on the fact that the licensee has been convicted of a crime. Further, anything that may be characterized as “misconduct” may be the foundation of a complaint and disciplinary action. Health care fraud allegations that have resulted in either a criminal conviction or have been settled civilly may therefore form the basis of a licensing board’s investigation and/or a professional society’s disciplinary proceedings.

Fraud Alerts

Beginning in 1989, the Office of Inspector General began to issue special “fraud alerts” designed to inform the health care industry about conduct that potentially violates fraud and abuse laws. The following is a brief summary of the Special Fraud Alerts that impact the physician community:

- **SPECIAL FRAUD ALERT ON JOINT VENTURE AND CONTRACTUAL ARRANGEMENTS.** In August 1989, the OIG issued an alert on joint ventures and contractual arrangements between providers, which included a description of “indicators of potentially unlawful activity” in three aspects of a joint venture: investors, business structure and financing and profit distributions.
- **SPECIAL FRAUD ALERT ON ROUTINE WAIVER OF CO-PAYMENTS OR DEDUCTIBLES.** In May 1991, the OIG issued an alert to advise the health care industry that it would be investigating providers, such as physicians, who are paid on the basis of charges and routinely waive (do not bill) Medicare deductibles and co-payment charges to beneficiaries for services and items covered by the Medicare program. The OIG opined that such systemic conduct results in false claims, violations of the Anti-Kickback Statute, and excessive utilization of services and items paid for by Medicare.
- **SPECIAL FRAUD ALERT ON HOSPITAL INCENTIVES TO REFERRING PHYSICIANS.** In May 1992, the OIG identified suspect arrangements between hospitals and physicians involving incentives to physicians to refer patients to the hospital. These include incentives that reduce physician’s professional expenses (discounted office space or free staff services) or increase physician revenue (hospital payment each time the physician refers a patient to the hospital).
- **SPECIAL FRAUD ALERT ON ARRANGEMENTS FOR THE PROVISION OF CLINICAL LAB SERVICES.** In October 1994, the OIG discussed how certain arrangements between physicians or other health care providers and outside clinical laboratories to which they refer patient specimens may implicate the Anti-Kickback Statute. The alert notes arrangements involving phlebotomists from a laboratory placed in a physician’s office may implicate the statute if additional services are rendered for the physician. Other situations mentioned include discounts for referrals, waiver of charges to managed care patients, free pick-up and disposal of biohazardous waste products, and free testing for health care providers, their families, and their employees.
- **SPECIAL FRAUD ALERT ON HOME HEALTH FRAUD.** In June 1995, the OIG identified suspect kickback arrangements initiated by home health providers with physicians, beneficiaries, hospitals, and rest homes in return for referrals, fraud in annual cost reports, false billing practices, and claims for services not rendered. Suspect arrangements for referrals include offering free services and disguising referral fees as salaries by paying for services not rendered or in excess of fair market value, among others.
- **PHYSICIAN LIABILITY FOR CERTIFICATIONS IN THE PROVISION OF MEDICAL EQUIPMENT AND SUPPLIES AND HOME HEALTH SERVICES.** In January 1999, the OIG issued this alert to make physicians more aware of the

significance of certifications of medical necessity for durable medical equipment or home health care and how it could contribute to fraud and abuse and overutilization of health care services. The alert gives examples of inappropriate certifications that the OIG's investigations uncovered, such as a physician knowingly signing a number of forms falsely representing that services are medically necessary in order to qualify the patient for home health services; a physician falsely certifying that a patient is confined to the home and qualifies for home health services; a physician signing a stack of blank Certificates of Medical Necessity (CMNs) to be completed with false information in support of fraudulent claims for the equipment, among others. The alert is also careful to say that physicians are not personally liable for erroneous claims due to mistakes, inadvertence, or simple negligence.

- **SPECIAL FRAUD ALERT ON RENTAL OF SPACE IN PHYSICIAN OFFICES BY PERSONS OR ENTITIES TO WHICH PHYSICIANS REFER.** Issued in February 2000, this alert identifies arrangements for physician office rental space that may possibly be disguised kickbacks to induce referrals. These arrangements include “comprehensive outpatient rehabilitation facilities” (CORFs) that provide physical and occupational therapy and speech-language pathology services in physicians’ and other practitioners’ offices; mobile diagnostic equipment suppliers that perform diagnostic-related tests in physicians’ offices; and suppliers of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that set up “consignment closets” for their supplies in physicians’ offices. The OIG focuses on three features of suspect rental arrangements: (1) the appropriateness of rental agreements (e.g., whether payments of rental has traditionally been provided for free or for a nominal charge); (2) the rental amounts (e.g., in excess of fair market value based on certain factors); and (3) “time and space considerations” (e.g., unreasonable or unnecessary for a commercially reasonable business purpose of the supplier-tenant). The OIG also gives specific guidance as to how rental calculations may be made for appropriate “time and space considerations.” Lastly, the alert “strongly recommend[s] that parties to rental agreements between physicians and suppliers to whom the physicians refer or for which physicians otherwise generate business make every effort to comply with the space rental safe harbor to the Anti-Kickback Statute. . .”

CHAPTER 3 ~ Fraud and Abuse Initiatives by the Federal OIG

Risk Areas Identified in the OIG's Compliance Program Guidance for Individual and Small Physician Practices

In its Compliance Program Guidance for Individual and Small Group Physician Practice, the OIG identified specific “risk areas” that it focuses on during investigations of physicians.

CODING AND BILLING. The OIG reports that the following risk areas associated with billing have been among the most frequent subjects of investigations and audits:

- Billing for items or services not rendered or not provided as claimed. For example, an ophthalmologist billed for laser surgery he did not perform. As one element of proof, he did not even have laser equipment or access to such equipment at the place of service designated on the claim form where he performed the surgery.
- Submitting claims for equipment, medical supplies, and services that are not reasonable and necessary. This involves seeking reimbursement for a service that is not warranted by a patient's documented medical condition.
- Double billing resulting in duplicate payment. Double billing occurs when a physician bills for the same item or service more than once. Although duplicate billing can occur due to simple error, the knowing submission of duplicate claims, which is sometimes evidenced by systematic or repeated double billing, can result in liability.
- Billing for non-covered services as if covered. For example, Dr. Y bills Medicare using a covered office visit code when the actual service was a non-covered annual physical. Physician practices should remember that “necessary” does not always constitute “covered” and that this example is a misrepresentation of services to the federal health care programs.
- Knowing misuse of provider identification numbers that results in improper billing. An example of this is when the practice bills for a service performed by Dr. B, who has not yet been issued a Medicare provider number, using Dr. A's Medicare provider number. Physician practices need to bill using the correct Medicare provider number, even if that means delaying billing until the physician receives his or her provider number.
- Unbundling Comprehensive Procedure Codes. Unbundling is the practice of a physician billing for multiple components of a service that must be included in a single fee. For example, if dressings and instruments are included in a fee for a minor procedure, the provider may not also bill separately for the dressings and instruments.
- Failure to properly use coding modifiers. A modifier, as defined by the CPT-4 manual, provides the means by which a physician practice can indicate when a service or procedure that has been performed has been altered by some specific circumstance but not changed in its definition or code.
- Clustering. This is the practice of coding/charging one or two middle levels of service codes exclusively, under the philosophy that some will be higher, some lower, and the charges will average out over an extended period. In reality, this overcharges some patients while undercharging others.

- Upcoding the level of service provided. Upcoding is billing for a more expensive service than the one actually performed. For example, Dr. X intentionally bills at a higher E&M code than what he actually renders to the patient.

REASONABLE AND NECESSARY SERVICES. The OIG recognizes that physicians should be able to order any tests, including screening tests, they believe are appropriate for the treatment of their patients. However, a physician practice should be aware that Medicare will only pay for services that meet the Medicare definition of reasonable and necessary. "... for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

DOCUMENTATION. Timely, accurate, and complete documentation is important to clinical patient care. This same documentation serves as a second function when a bill is submitted for payment, namely, as verification that the bill is accurate as submitted. The following are some guidelines identified by the OIG to ensure accurate medical record documentation:

- The medical record should be complete and legible.
- The documentation of each patient encounter includes 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 who has appropriate medical training.
- CPT and ICD-9-CM codes used for claims submission should be supported by documentation and the medical record.
- 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 is documented.

HCFA 1500 FORM. Another documentation area for physician practices to monitor closely is the proper completion of the HCFA 1500 form. The OIG opines that the following practices will help ensure the form has been properly completed:

- Link the diagnosis code with the reason for the visit or service.
- Use modifiers appropriately.
- Provide Medicare with all information about a beneficiary's other insurance coverage under the Medicare Secondary Payer (MSP) policy if the practice is aware of a beneficiary's additional coverage.

IMPROPER INDUCEMENTS, KICKBACKS, AND SELF-REFERRALS. The Anti-Kickback Statute provides criminal penalties for individuals and entities that knowingly offer, pay, solicit, or receive bribes or kickbacks or other remuneration in order to induce business reimbursable by federal health care programs. 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 for referrals. 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. Civil penalties, exclusion from participation in the federal health care programs, and civil False Claims Act liability may also result from a violation of the prohibition.

The physician self-referral law (also known as the Stark Law) prohibits a physician from making a referral to an entity with which the physician or any member of the physician's immediate family has a financial relationship if

the referral is for the furnishing of designated health services, unless the financial relationship fits into an exception set forth in the statute or implementing regulations.

In particular, arrangements with hospitals, hospices, nursing facilities, home health agencies, durable medical equipment suppliers, pharmaceutical manufacturers and vendors are areas of potential concern. In general, the Anti-Kickback Statute prohibits knowingly 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 in which physician practices refer business to, or order services or items from, an outside entity should be on a fair market value basis. The OIG's definition of "fair market value" excludes any value attributable to referrals of federal program business or the ability to influence the flow of such business. Adhering to the rule of keeping business arrangements at fair market value is not a guarantee of legality, but it is a highly useful general rule. Whenever a physician practice intends to enter into a business arrangement that involves making referrals, the arrangement should be reviewed by legal counsel familiar with the anti-kickback and physician self-referral statutes.

In addition to developing standards and procedures to address arrangements with other health care providers and suppliers, physician practices should also consider implementing 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. In the OIG Special Fraud Alert "Routine Waiver of Medicare Part B Co-payments/Deductibles" (May 1991), the OIG describes several reasons why routine waivers of these cost-sharing amounts pose concerns. The alert sets forth the circumstances under which it may be appropriate to waive these amounts.

OIG's Fiscal Year 2002 Work Plan

Each year, the OIG publishes its annual work plan, which highlights the areas that will be the focus of enforcement during the coming fiscal year. In the OIG's Fiscal Year 2002 Work Plan, the following are some of the focus areas affecting physicians:

ADVANCE BENEFICIARY NOTICES. Physicians must provide advance notices before they provide services that they know or believe Medicare does not consider medically necessary or that Medicare will not reimburse. Beneficiaries who are not notified before they receive such services are not responsible for payment. As a result, the OIG intends to examine the use of advance notices to Medicare beneficiaries and their financial impact on beneficiaries and providers.

PHYSICIAN EVALUATION AND MANAGEMENT CODES. The OIG will continue its initiative to determine whether physicians correctly coded E&M services in physician offices and effectively used documentation guidelines.

CONSULTATIONS. The OIG will determine the appropriateness of billings for physician consultation services.

SERVICES AND SUPPLIES INCIDENT TO PHYSICIANS' SERVICES. Physicians may bill for the services provided by allied health professionals such as nurses, technicians, and therapists as incident to their professional services. Incident-to services, which are paid at 100 percent of the Medicare physician fee schedule, must be provided by an employee of the physician and under the physician's direct supervision. The OIG will investigate the quality and appropriateness of these billings.

REASSIGNMENT OF BENEFITS. The OIG will examine the use of staffing companies and how this practice affects emergency department physicians to identify any vulnerabilities in relation to Medicare reassignment rules.

PHYSICIANS AT TEACHING HOSPITALS. The OIG is continuing its initiative to verify compliance with Medicare rules governing payment for physician services provided in the teaching hospital setting to ensure that claims accurately reflect the level of service provided to patients.

BILLING FOR RESIDENTS' SERVICES. Medicare regulations allow residents, who are licensed physicians, to be issued physician identification numbers for purposes of billing Medicare for their services. Residents may bill Medicare only when they are “moonlighting,” which is defined as providing medical treatment, other than in their field of study, in an outpatient clinic or an emergency room. The OIG will determine whether hospitals have improperly used residents' physician identification numbers to bill Medicare.

Other physician areas in the work plan include the following:

- Inpatient Dialysis Services
- Bone-Density Screening

Additional Risk Areas Identified by the OIG in the Compliance Program Guidance for Individual and Small Physician Practices

In an appendix to the Compliance Program Guidance for Individual and Small Group Physician Practices, the OIG identified a number of additional “risk areas” that a physician practice should address during the development of a compliance program.

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.

ADVANCE BENEFICIARY NOTICES (ABN). Physicians are required to provide ABNs before they provide services that they know or believe Medicare does not consider reasonable and necessary. 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. A common risk area associated with ABNs is in regard to diagnostic tests or services. The ABN must be sufficient to put the patient on notice of the reasons why the physician believes that 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

- Be in writing;
- Identify the specific service that may be denied (procedure name and CPT/HCPC code is recommended);
- State the specific reason why the physician believes the service may be denied; and
- Be signed by the patient acknowledging that the required information was provided and the patient assumes responsibility to pay for the service.

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.

PHYSICIAN INCENTIVE ARRANGEMENTS. The OIG has identified potentially illegal practices involving the offering of incentives by hospitals and other 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; and
- Guarantees that if the physician's income fails to reach a predetermined level, the entity will supplement the remainder up to a certain amount.

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 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 OIG has a longstanding concern that such arrangements may increase the risk of intentional upcoding and similar abusive billing practices.

PROFESSIONAL COURTESY. The term "professional courtesy" is used to describe a number of 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. The following are general observations made by the OIG 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 co-payments 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. However, such a practice of waiving co-payments would implicate the prohibition of inducements to patients if the patient for whom the co-payment is waived is a beneficiary of a federal health care program who is not financially needy.

CHAPTER 4 ~ Fraud and Abuse Compliance Program Forms

Sample Fraud and Abuse Compliance Program

1. Policy Statement (TC\L1"1 policy statement)

The Practice is committed to compliance with applicable health care laws and third-party payer requirements. To this end, this Fraud and Abuse Compliance Program has been approved by the Practice's [Board of Directors]. The Practice intends for its employees to use this Program as a guide in its continuing efforts to comply with applicable federal, state, and third-party payer laws, rules, regulations, and policies. It is recognized that, in practice, complete perfection in the area of compliance may not be truly attainable. However, it is the Practice's goal to strive for excellence and use good faith efforts in its compliance activities.

The Standards of Conduct set forth in this Program contain the principles and standards to which employees of the Practice are expected to adhere. The purpose of the Standards of Conduct is to articulate the ethical and legal framework within which the Practice operates and to advise employees that they are required to abide by these Standards. Employees are urged to seek guidance from the Compliance Officer regarding any compliance matter. Employees are also required to report perceived violations of the Standards of Conduct to the Compliance Officer.

The failure of an employee to observe the provisions of this Program can result in serious consequences for the Practice, including criminal prosecution, substantial criminal and civil monetary fines, and damage to its professional reputation. Likewise, the failure of an employee to report perceived violations of the Program or related policies can result in consequences for the employee, including various levels of corrective action, or other disciplinary actions, which may include termination.

2. Compliance with Documentation, Coding, Billing and Related Statutes, Regulations, and Policies (TC\L2"4 Compliance with Billing and Related Statutes, Regulations, and Policies)

The Practice is committed to compliance with the documentation, coding, and billing requirements of the federal government, state government, and other third-party payers. It is the Practice's policy to submit claims for payment that are properly coded to accurately reflect the services provided, that the services are reasonable and necessary, that the coded services and diagnosis are supported in the medical record documentation and are submitted in the name of the appropriate provider. Accordingly, the Practice has adopted this Program to prevent and detect violations of the statutes, regulations, rules, and policies of the various payers relating to documentation, billing, and coding. The Practice will monitor any compliance issues it may have and implement appropriate corrective action to address identified problems.

3. Compliance Officer

The [Board of Directors] has appointed _____ [insert name] as Compliance Officer to serve as the focal point for compliance. The Compliance Officer is accountable to [the Board] and coordinates the Practice's compliance efforts. The Compliance Officer is responsible for overseeing implementation of the Program, recommending changes in practice to enhance compliance, the daily operation of the Program, and updating the Program.

4. Standards of Conduct

The Practice expects all employees to conduct business in an ethical, legal, and competent manner. All employees shall use reasonable good faith efforts to comply with this Program and to maintain a high level of integrity and honesty in their dealings with the Practice and third parties. Employees shall avoid any conduct that could reflect adversely on the integrity of the Practice.

All physicians and employees shall honestly and accurately document any services provided, describing the service actually rendered and the person rendering the service in an appropriate manner. All physicians shall take steps to ensure that only services that are medically necessary are billed to third-party payers. All coding of charges shall fairly reflect only the services documented to have been actually rendered, and all charges will be coded according to applicable billing regulations.

The Practice expects its employees to refrain from conduct that may violate the laws related to health care fraud and abuse. These laws prohibit, among other matters, (1) the submission of false, fraudulent, or misleading claims to any governmental entity or third-party payer; (2) making false representations to any person or entity in order to obtain payment for a service; and (3) direct, indirect, or disguised payments in exchange for the referral of patients.

Examples of activities at risk for charges of unlawful coding and billing include

- Billing for services not actually rendered,
- Billing for non-covered services as if covered,
- Providing medically unnecessary services,
- Knowing misuse of provider numbers,
- Upcoding the level of service provided,
- Duplicate billing that results in duplicate payment, and/or
- Unbundling a global or all-inclusive fee.

5. Education

All employees will be trained on the Compliance Program and their responsibilities with regard to the Program. In addition, employees will be provided with ongoing compliance education and training as appropriate. These educational efforts will focus on the importance of compliance with all applicable statutes, rules, regulations, and policies, together with training regarding documentation, coding, and billing requirements.

6. Internal Reporting and Corrective Action

Compliance with the law and this Program is the duty and responsibility of every employee, and it is a condition of continued employment.

Any physician or employee with documentation, coding, billing, or related questions should seek clarification from the Compliance Officer. Additionally, any employee who believes that a violation of law or inappropriate conduct has taken place shall report the matter to the Compliance Officer in any manner that is comfortable to the reporter, including making an anonymous written report. The Practice will treat all reports confidentially to the extent reasonably possible. It is the policy of the Practice to take all reports of violations, inappropriate conduct, or wrongdoing seriously. No one who makes a report in good faith will be subjected to reprisal, discipline, or discrimination based on having made a report.

The Compliance Officer shall promptly investigate any report of suspected wrongdoing. Appropriate corrective action will be taken regarding any violations that may have occurred. Such action may, as appropriate, require changes in documentation, coding and billing policies or procedures; additional training for physicians, billing, or administrative personnel; the repayment of any overbilling, or disclosure to the third-party payer. In addition, when appropriate, disciplinary action may be taken against any employee responsible for the violation.

7. Auditing and Monitoring

The Practice will conduct periodic audits of a sampling of claims to determine its compliance with applicable documentation, coding, and billing requirements. If the audit shows inaccurate billings, insufficient documentation, or other problems, appropriate corrective action will be taken. This may include communication with the physician or other employee, education, and changes in procedure, together with the repayment of any overbilling or disclosure to the third-party payer. As part of its compliance efforts, the Practice will conduct necessary monitoring in response to specific complaints or reports of inaccurate or inappropriate billing.

8. Disciplinary Action

As an integral component of this Program, disciplinary action will be taken for failure to comply with or participate in the Practice's compliance efforts, including the failure to comply with applicable laws and regulations, the failure to report suspected violations of the program or applicable laws or regulations, and/or retaliation of any kind against an employee who makes a good faith report of suspected wrongdoing. Discipline may include any or all of the following depending on the severity of the situation: written warning or reprimand, required educational training, suspension, demotion, discharge, and voluntary disclosure to the appropriate federal and/or state governmental agencies.

9. Government Investigations

It is the policy of the Practice to comply with the law and to cooperate with any reasonable demand made in a government investigation. In cooperating with these government demands, however, it is imperative that the Practice's legal rights, and those of its employees, are fully protected to the extent of the law. If any employee receives an inquiry, subpoena, or other legal document relating in any way to the Practice or its business, whether at home or in the workplace, from any governmental agency, the employee is requested to immediately notify the Compliance Officer and/or the Practice's legal counsel. If an employee is visited at home by a governmental agent relating in any way to the Practice, the employee is legally entitled to ask the agent to return and is requested to immediately contact the Compliance Officer and/or the Practice's legal counsel to discuss the matter. The Practice may arrange for its legal counsel to accompany an employee to any government interview.

APPROVED AND ADOPTED: _____, 2003

Compliance Statement

_____ [Name of Practice]
recognizes its responsibility to comply with all applicable federal and state laws and the program requirements of federal, state, and private health plans. All professional, management, and support staff similarly acknowledge a responsibility to strive for the highest degree of ethical conduct and principles in relation to these program requirements and standards.

As a member of _____ [Name of Practice],
I am obligated to support its compliance policies. I further agree to comply with all practice policies and procedures to the best of my understanding and demonstrate a commitment to honest and responsible corporate conduct.

In keeping with these tenets of ethical practice and conduct, I acknowledge receipt of the Fraud and Abuse Compliance Program, that I have received training in my responsibilities under the Fraud and Abuse Compliance Program, and recognize an obligation to report any erroneous or potentially improper procedures that I am of aware of or suspect to the Practice's Compliance Officer.

Name (Please Print) _____

Title/Position _____

Signature _____

Date _____

Fraud and Abuse Compliance Program Educational Handbook (In-Service Training)

The Importance of the Medicare and Medicaid System to Physicians

Much of the gross revenue of every physician practice is derived from the federal Medicare and state Medicaid programs. Participation in these programs requires strict adherence to their various rules and regulations. Failure to follow Medicare/Medicaid rules can result in criminal prosecution, civil fines, and even exclusion from the Medicare and Medicaid programs.

Example: Civil monetary penalties can be assessed by the government at \$10,000 per item or service. Thus, even where an inappropriately billed claim is for a nominal amount (under \$100), the \$10,000 penalty is applied. Ten bad claims, therefore, can result in a \$100,000 civil penalty.

The seriousness of complying with these rules is most evident when considering the fact that violations can result in exclusion from participation in the Medicare and Medicaid programs.

Overview of Fraud and Abuse Laws

There are a number of statutes dealing with health care fraud and abuse. The following are two of the most important federal laws relating to physician services:

1. FALSE CLAIMS ACT

The phrase “false claim” is defined as

Knowingly and willfully making or causing to be made any false statement or representation of material fact in any application (claim) for benefits or payments under a federal health care program (including Medicare or Medicaid).

Examples for physicians:

- Billing for services never provided to patients.
- “Upcoding”: billing for more extensive services than were actually rendered.
- Falsely certifying that services were medically necessary.

Note: On every HCFA 1500 claim form, a physician must certify that the services rendered were medically necessary for the health of the beneficiary.

- Flagrant and persistent over utilization of medical services with little or no regard for results and/or the patient’s ailments, condition, or medical needs.

2. ANTI-KICKBACK STATUTE

This statute prohibits

The knowing and willful solicitation or receipt of any remuneration (this includes payments and anything else of value) or the knowing and willful offer to pay, or payment of any remuneration, whether direct or indirect, overt or covert, in cash or in kind, in return for

- Referring an individual for any item or service or
- Purchasing, leasing, ordering, or arranging for or recommending or arranging for the purchase, lease, or ordering of any item of service paid for (in whole or in part) under a federal health care program.

The general purpose of this statute is to prohibit anyone from paying or accepting a payment in exchange for the referral of a patient for services that might be covered by the Medicare and Medicaid programs.

What this means is that you cannot give gifts or anything of value in order to induce referrals to the Practice.

Furthermore, the opposite is also true: You cannot accept gifts or things of value from a vendor in order to do business with him. Examples: cash, vacations, gift certificates, etc.

Other examples:

- Waiving co-payments or deductibles for patients unless the patient meets financial hardship guidelines.
- Financial arrangements with third parties, such as a home health agency, to whom the Practice may refer patients.

3. CIVIL SANCTIONS FINES AND EXCLUSIONS

Apart from potential criminal prosecution, there are additional, noncriminal sanctions that may be separately imposed for nonconforming conduct. Generally, civil (noncriminal) sanctions include fines and/or exclusion from participation in the Medicare and Medicaid programs.

Exclusions from participation in the Medicare and Medicaid programs can result from a conviction for health care fraud or other impermissible conduct. If a provider is excluded from the Medicare or Medicaid programs, it means that no Medicare or Medicaid payments will be made for any services rendered by the excluded party.

Civil money penalties can also be imposed for violations of the fraud and abuse laws. These may be in addition to criminal penalties.

Civil money penalties of up to \$10,000 per item or service, plus an assessment of up to three times the amount claimed for each such item or service, may be imposed upon any provider who knowingly presents or causes to be presented a claim for Medicare or Medicaid reimbursement that

- Is for an item or service that the person knows or should know was not provided as claimed or
- Is for an item or service and the person knows or should know the claim is false or fraudulent.

Sample Code of Conduct Relating to Coding and Billing Practices

It is the Practice's policy to make and maintain accurate and honest records relating to all services, to submit accurate billings to all payers (including Medicare and Medicaid), and to comply with all laws and regulations relating to Medicare and Medicaid coding and billing practices. In furtherance of this policy, the Practice bills only for services that are actually rendered, codes accurately, documents medical necessity and appropriateness, and complies with all payer contracts.

The Practice expects all employees to conduct business in an ethical, legal, and competent manner. Employees shall maintain a high level of integrity and honesty in their dealings with the practice and third parties. It is also expected that employees avoid any conduct that could reflect adversely on the integrity of the practice.

The Practice expects its employees to refrain from conduct that may violate the fraud and abuse laws. These laws prohibit, among other matters, (1) direct, indirect, or disguised payments in exchange for the referral of patients; (2) the submission of false, fraudulent, or misleading claims to any governmental entity or third-party payer; and (3) making false representations to any person or entity in order to obtain payment for a service.

All physicians and employees shall honestly and accurately document any services provided, describing the service actually rendered and the person rendering the service in an appropriate manner. All physicians shall take steps to ensure that only services that are medically necessary are billed to third-party payers. All coding of charges shall fairly reflect only the services documented to have been actually rendered, and all charges will be coded according to applicable billing regulations.

Risk Areas Identified by the Office of Inspector General

The Office of Inspector General has identified the following "risk areas" that are frequently the subject of investigations and audits of physician practices:

- Billing for services not actually rendered;
- Billing for medically unnecessary services;
- "Upcoding" the level of service provided;
- Duplicate billing resulting in duplicate payment;
- Billing for non-covered services as if covered;
- Unbundling (billing for each component of a service instead of billing an all-inclusive code);
- Knowing misuse of provider numbers;
- Failure to refund credit balances; and/or
- Physician self-referral law (the Stark Law).

(Practice should insert other applicable risk areas following a baseline review)

Overview of the Fraud and Abuse Compliance Program

- The Practice has developed a Fraud and Abuse Compliance Program that is applicable to each and every physician and employee of the Practice. Basically, it is a written expression of the Practice's policy to comply with both the letter and spirit of the law.
- The Practice encourages the highest level of ethical behavior by its physicians and staff, and the Practice encourages and requires compliance with the law.
- It is important that each and every employee understand that compliance is mandatory.

Compliance Program Components

- Code of Ethical Conduct
- Appointment of Compliance Officer
- Employee Education Policy
- Employee Participation and Reporting
- Monitoring and Auditing
- Investigation and Remediation
- Disciplinary Action
- Government Investigations
- Employee/Vendor Screening Policy

CODE OF ETHICAL CONDUCT

- Sets forth the requirement that physician and staff conduct themselves ethically and comply with all laws and regulations.
- Sets forth the Practice's policy to submit claims for payment that are properly coded to accurately reflect the services provided, that the services be reasonable and necessary, that the coded services and diagnosis be supported in the medical record documentation, and that claims be submitted in the name of the appropriate provider.

APPOINTMENT OF COMPLIANCE OFFICER

- _____ has been appointed Compliance Officer for the Practice.
- The Compliance Officer is responsible for overseeing and monitoring the Compliance Program.
- The Compliance Officer is the person to go to with any questions about documentation, coding, or billing matters.
- The Compliance Officer has the authority to enforce standards and to implement corrective actions.

EMPLOYEE EDUCATION POLICY

- All employees are required to undergo continued training and education to ensure compliance with applicable laws and regulations relating to the Practice.
- In addition, employees will participate in ongoing education activities regarding compliance, coding, and billing issues.

EMPLOYEE PARTICIPATION AND REPORTING

- The most important factor in the success of any compliance program is participation by the employees.
- It is the responsibility of all employees to prevent unsafe, unethical, illegal, and inappropriate conduct and, when such conduct is discovered, to report the conduct to the Compliance Officer.
- Any time you have a good faith belief that something is not being done properly, you must report your concerns to the Compliance Officer. If you request, the Practice will attempt to keep your name confidential while your complaint is being investigated. If you are uncomfortable with speaking directly to the Compliance Officer, you can do so anonymously by writing a note to the Compliance Officer.
- Any employee who believes in good faith that a violation or erroneous conduct has taken place should report the matter. This can also involve just generalized concerns about the claim development and submission process: The Practice encourages you to ask questions and bring any concerns you have to the Compliance Officer.
- Suspected violations can be reported in any manner that is comfortable for the reporter, including telling the Compliance Officer about the violation either orally or in writing.
- Suspected violations can also be reported anonymously by dropping written concerns in the designated drop box located at the Practice's office. The Practice will treat all reports confidentially to the extent reasonably possible.
- It is the policy of the Practice to take all reports of violations or wrongdoing seriously.
- Whether a violation is the result of an innocent mistake or planning and intent, it is important that all employees take responsibility for bringing the violation to the attention of the Compliance Officer or other person who can act to correct the situation.
- The early reporting of improper activity can only benefit the practice. It may help to avoid criminal or civil liability or exclusion from the Medicare or Medicaid program, all of which will result in damage both to the Practice's reputation and its ability to continue operating. Voluntary disclosure of problems is a factor considered by government agencies in determining any punishment to be imposed.
- The Practice will not tolerate any retaliation or retribution of any kind against an employee who makes a good faith report of suspected wrongdoing.
- Any such retaliation or retribution will, in itself, be grounds for discipline.

MONITORING AND AUDITING

- As part of the Compliance Program, the Practice will conduct periodic audits to assist in its efforts to monitor the accuracy of claims and other functions.
- At a minimum, the audits will consist of a review of a sampling of claims for each physician and submitted to each federal program, such as Medicare and Medicaid.
- The Practice may engage an outside auditor to review a representative sampling of claims on a periodic basis.
- In any case, where incorrect billing has occurred, appropriate corrective action will be taken.

INVESTIGATION AND REMEDIATION

- All complaints of inappropriate conduct will be promptly investigated. The principal purpose is to
 - Find out if in fact the Medicare and Medicaid or other laws, rules, and standards have not have been followed;
 - Determine whether any reported unethical, illegal, abusive, or neglectful conduct has occurred;
 - Identify the individuals who either knowingly or inadvertently were involved in the violation; and
 - Take appropriate action to correct any practices that violate the Medicare or Medicaid laws, rules, and standards.

DISCIPLINARY ACTION

- No matter what a person's title or job responsibilities, disciplinary action will be taken for violation of the Practice's fraud and abuse policies.
- Employees may be subject to discipline for failing to participate in the Practice's compliance efforts as follows:
 - Failure to comply with applicable laws or regulations;
 - Failure to report suspected violations of the Compliance Program or applicable laws or regulations to the Compliance Officer;
 - Failure of management to act on complaints or otherwise fail to implement corrective action after a violation has been established; and/or
 - Retaliation or retribution against any employee making a good faith report of suspected wrongdoing.
- Discipline may include any or all of the following depending on the severity of the situation: written warning or reprimand, required educational training, suspension, demotion, discharge, and voluntary disclosure to the appropriate federal and/or state governmental agencies.

GOVERNMENT INVESTIGATIONS

- The Practice will comply with all reasonable requests for information from government officials, subject to applicable privileges.
- If any employee receives an inquiry, subpoena, or other legal document relating in any way to the Practice or its business, whether at home or in the workplace, from any governmental agency, the employee is requested to immediately notify the Compliance Officer.
- If the employee is visited at home by a governmental agent relating in any manner to the Practice, the employee is legally entitled to ask the agent to return at a later time. You are encouraged to immediately contact the Compliance Officer.

EMPLOYEE/VENDOR SCREENING POLICY

- As part of the Compliance Program, the Practice will screen all employees, including physicians, to determine whether they have been convicted of a health care offense or been excluded from federal health care program participation.
- It is the Practice's policy to not employ any individual convicted of a health care offense or who has been excluded from participation in the Medicare and Medicaid programs.

- Similarly, the Practice will not knowingly contract with or do business with any person or entity convicted of a health care offense or excluded from federal program participation.

Outline of Compliance Officer Responsibilities

Responsibility for All Compliance Activities

The Compliance Officer coordinates the Practice's compliance efforts. The Compliance Officer is responsible for overseeing implementation of the Program, making recommendations to the [Board of Directors] regarding changes in practice to enhance compliance, the daily operation of the Program, and updating the Program.

Conducting a Legal Review of Contractual Arrangements

The Compliance Officer shall have legal counsel review all existing and proposed contracts with vendors and others to insure the arrangements comply with the Anti-Kickback Statute and the Stark Law regarding physician self-referrals.

Maintaining a Compliance Notebook of All Compliance Activities

The Compliance Officer shall maintain a Compliance Notebook to document all compliance activities. It should contain separate sections regarding training and education, educational bulletins, audits, employment screening, investigation of suspected violations, and disciplinary actions.

The Compliance Officer shall keep a record of all compliance-related activities, including records of compliance meetings, educational activities, and internal audit results. In addition, the Compliance Officer shall document any violations uncovered by the Compliance Program and the resulting remedial action taken.

Maintaining a Policies and Procedures Binder

The Compliance Officer should maintain a resource binder that contains the Practice's written policies and procedures. In addition, the binder should include relevant materials relating to documentation, coding, and billing such as relevant Medicare directives and/or bulletins from the Medicare carrier, Medicaid, and other insurance programs, together with summaries of applicable fraud alerts and advisory opinions issued by the OIG.

Retention of Acknowledgements of Receipt of Compliance Program Materials and Training

The Compliance Officer shall retain the original signed acknowledgements of receipt from each employee of Fraud and Abuse Compliance Program, educational training materials, and attendance at the initial training session.

Documenting Advice from Medicare or Other Payers

Any time a member of the billing staff telephones the Medicare carrier or other third-party payer with a billing or other question, a record should be made of the telephone call, noting the date and time, name and telephone number of the person spoken to, the issue raised, and the response made.

In addition, for any inquiry about a billing situation that is likely to recur, it is advised that the telephone conversation be followed up with a letter detailing the issue raised and the advice that was given. All such letters and correspondence shall be maintained by the Compliance Officer.

Annual Review of OIG Initiatives

On an annual basis, the Compliance Officer should review the OIG's current work plan and semiannual reports to identify any additional risk area applicable to the Practice. These documents are available on the OIG's website at <http://oig.hhs.gov/publications.html>.

Employee Education Policy

It is the responsibility of the Compliance Officer to provide employees with such training as may be reasonably necessary and appropriate to ensure material compliance with applicable laws relating to the submission of claims or the practice's business. The Compliance Officer may designate a member of the staff to be responsible for communicating new information regarding coding, billing, documentation, and other compliance matters to all staff and employees of the practice.

1. **NEW EMPLOYEES.** All new employees will be provided with a copy of the Fraud and Abuse Compliance Program and appropriate educational training materials.
2. **ANNUAL TRAINING.** The OIG recommends that refresher training on compliance matters be conducted on an annual basis or as appropriate. At a minimum, it is recommended that all coding and billing personnel receive annual retraining.
3. **CONTINUED TRAINING.** On a routine basis, the Compliance Officer should address compliance, coding, and documentation issues at regular staff meetings. Such education at these meetings can include examples of coding or documentation problems found in recent monitoring efforts and a discussion of the proper ways to handle such issues. The minutes of the meetings should reflect the compliance topics discussed.

The Compliance Officer should communicate any new information regarding billing and compliance to the staff, including a review of fraud alerts and newsletters, and provide a summary of any relevant information to the staff and employees.

The Compliance Officer shall encourage all billing, coding, and management personnel to attend Medicare carrier or other payer-sponsored educational sessions, seminars, workshops, or similar education sessions relating to the claim development and submission process.

4. **DOCUMENTATION OF COMPLIANCE TRAINING.** All documentation, coding, and billing compliance education shall be thoroughly documented, including maintaining copies of all e-mail, memoranda, and training materials. Additionally, documentation of attendance at staff meetings (agenda, minutes, and attendance list) should also be maintained.

The training provided to each employee shall be documented by the Compliance Officer. The documentation shall include the name and position of the employee, the date and duration of the educational activity or program, and a brief description of the subject matter. A copy shall be placed in the employee's personnel file and maintained in the Compliance Notebook as well.

Conducting Exit Interviews

The Compliance Officer should conduct an exit interview of any employee leaving the practice to solicit information about whether the employee has any information concerning violations of the compliance program, or any issues relating to the fraud and abuse, or ethical issues or concerns about any aspect of the Practice.

Monitoring and Auditing

In furtherance of its obligations as a participant in Medicare and other government-funded health care payment programs, the Practice will conduct periodic audits to assist in its efforts to monitor the accuracy of coding and billing.

A representative sample of claims will be periodically reviewed to allow the Practice to promptly identify deficiencies in the claim development and submission process that may result in inaccurate claims. The audit should be used to determine if

- Bills are accurately coded and accurately reflect the services provided;
- Services or items provided are reasonable and necessary; and
- The medical records contain sufficient documentation to support the charge.

A random sample of claims involving each physician (nurse practitioner or physician assistant) will be reviewed to determine compliance with the Medicare, Medicaid, and private payer billing requirements for coding, billing, and documentation. The audits will consist of a review of a minimum 2 to 5 records for each payer (including Medicare and Medicaid) and 5 to 10 claims for each physician (nurse practitioner or physician assistant) to ensure that the services billed were rendered and are accurately and completely documented.

In addition, these periodic audits will focus on the following items:

- A valid sample of the practice's top ten denials or the practice's top ten services provided;
- Confirmation that the practice is using specific codes for the presenting diagnosis;
- A check for data-entry errors;
- Confirmation that all orders are written and signed by a physician; and
- A review of assignment codes and modifiers to the claims.

Additionally, at the Compliance Officer's discretion, on an annual or other periodic basis, an outside auditor may be engaged to review a representative sampling of claims.

The Compliance Officer shall keep documentation regarding all reviews and audits, including a record of the particular claims reviewed and the outcome of each review.

Corrective Actions

As important as undertaking periodic reviews, the Compliance Officer must take appropriate actions in the event a deficiency or error is found.

First, there should be documented communication with the particular physician, nurse, billing staff, or other employee, and copies are to be filed with the physician's or employee's performance file. The Compliance Officer should also consider appropriate action, such as retraining the individual(s) involved, or disciplinary action.

Second, corrective actions should be taken, including submitting revised bills or applications for refunds. All identified overpayments should be promptly disclosed and refunded to the entity that made the erroneous payment. If problems are identified, a focused review should be conducted of the problem claims on a more frequent basis. In certain cases, a corrective action plan must be prepared, which lists each billing practice that may not meet all applicable requirements and specifies what will be done to correct it.

Finally, if a deficiency was the result of a systemic issue, consultation with legal counsel and notification of the carrier or third-party payer may be required. The Compliance Officer will document all interactions with the carrier in order to maintain a record of the Practice's compliance efforts.

Investigation of Complaints

In the event of a report by an employee, a third party, or other information concerning an activity which may be contrary to applicable laws or regulations or claims that may be submitted in a manner which does not meet the applicable program requirements, the Compliance Officer shall conduct an investigation as follows:

1. **PURPOSE OF INVESTIGATION.** The purpose of the investigation shall be to identify those situations in which the laws, rules, and standards of the Medicare or other third-party payer programs may not have been followed; to identify individuals who may have knowingly or inadvertently caused claims to be submitted or processed in a manner that violated such laws, rules, or standards; to facilitate the correction of any practices not in compliance with such laws, rules, and standards; to implement those procedures necessary to insure future compliance; and to protect the practice in the event of civil or criminal enforcement actions.
2. **INVESTIGATIVE PROCESS.** Upon receipt of an employee complaint or other information (including audit results) that suggests the existence of a serious pattern of conduct in violation of compliance policies or applicable laws or regulations, an investigation under the direction and control of the Compliance Officer and/or legal counsel shall be commenced. Suspected violations will be investigated as promptly and as discreetly as possible under the circumstances. In undertaking this investigation, the Compliance Officer may solicit the support of employees, external counsel and auditors, and other resources knowledgeable about the applicable laws and regulations and required policies, procedures, or standards that relate to the specific problem in question.
3. **CORRECTIVE ACTION.** Appropriate corrective action will be taken upon the conclusion of an investigation. If the employee who made the report or complaint identified himself/herself, the Compliance Officer will provide this employee with feedback concerning the review and the resolution of the allegation.
4. **DOCUMENTING THE INVESTIGATION.** The Compliance Officer shall thoroughly document how the investigation was conducted, including keeping a record of all persons interviewed and documents reviewed, together with any corrective action taken.

Discipline

Employees, including physicians, may be subject to discipline for failing to participate in the Practice's compliance efforts. Examples of conduct that could result in disciplinary action include the following:

1. The failure of an employee to perform any obligation relating to compliance with the Compliance Program or applicable laws or regulations;
2. The failure to report suspected violations of the Compliance Program or applicable laws or regulations to an appropriate person; or
3. Retaliation or retribution of any kind against an employee who makes a good faith report of suspected wrongdoing.

Discipline may include any or all of the following depending on the severity of the situation: written warning or reprimand, required educational training, suspension, demotion, discharge, and voluntary disclosure to the appropriate federal and/or state governmental agencies.

Employee/Vendor Screening Policy

An element of compliance is to have an “Employee/Vendor Screening Policy.” One of the responsibilities of the Compliance Officer listed in the OIG’s Compliance Program Guidance for Individual and Small Group Physician Practices is to insure that a reasonable inquiry is made into the background of prospective employees and vendors (such as billing agents) whose job function or activities may materially impact the Medicare/Medicaid claim development and submission process.

Individuals who have been convicted of a criminal offense related to health care or who have been debarred, excluded, or otherwise declared ineligible to participate in federally funded health care programs shall not be employed by the Practice. The following categories of prospective employees must be screened to determine whether they have been (a) convicted of a criminal offense related to health care or (b) listed by a federal agency as debarred, excluded, or otherwise ineligible for federal program participation:

- Any person occupying a management position;
- All employees with direct patient contact such as a physician, nurse, or staff member; and
- All billing and coding employees or supervisors and managers.

In addition, the Practice can not knowingly contract with or do business with any person or entity that has been (a) convicted of a criminal offense related to health care (unless such person or entity has implemented a compliance program as part of an agreement with the federal government) or (b) listed by a federal agency as debarred, excluded, or otherwise ineligible for federal program participation. As a result, the Practice must insure that any outside billing agent has not been excluded.

To make this determination, a search should be made of the OIG’s “List of Excluded Individuals/Entities” at the following website: <http://exclusions.oig.hhs.gov/>. In addition, a search should be made of the General Services Administration’s “List of Parties Excluded from Federal Procurement and Nonprocurement Programs” at <http://epls.arnet.gov>. In each case, the Compliance Officer should print a copy of the search result and place that printout in both the employee’s personnel file and in the Compliance Notebook.

CHAPTER 5 ~ Conclusory Remarks

Reducing the potential for inaccurate billing practices and creating a climate of compliance with the law are the primary reasons for implementing and maintaining a compliance plan. It is far less expensive to develop a compliance program to prevent mistakes from being made than to defend a Medicare post-payment audit based on a statistical sampling of paid claims that can result in a demand for repayment of an extrapolated amount of money. At the same time, the process of developing a compliance program allows the involved physicians to better understand how the practice is actually operating. In fact, the development of a compliance program is more akin to the implementation of an overall risk-management program for the practice.

Finally, physicians practicing in today's complex and highly regulated environment must realize that compliance means more than simply adopting a boilerplate document labeled compliance plan. The key to an effective compliance plan is for the practice to establish a culture of ethical behavior and compliance within the practice. Employees must understand that every member of the practice, from physicians to billing personnel and clerical staff, is expected to behave legally and ethically at all times.

Both employees and colleagues need to be encouraged to come forward with any questions they may have about billing issues or other business-related or patient-care matters that they do not understand or do not believe are being handled correctly. Not only should a practice have an "open door" policy, but it may wish to install a complaint/suggestion box for this purpose for timid or reluctant employees who may not want to raise an issue directly with the "compliance officer." In all cases, when an issue is raised, the practice must provide the individual with an honest answer and/or solution to the problem. Finally, employees should feel comfortable coming forward with a compliance issue or concern, without fear of retaliation.