COMPLIANCE PLAN
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COMPLIANCE PROGRAM OVERVIEW

Introduction

Pressures on all health care providers, including urologists and their practices, have increased steadily over the past several years. With the wide variety of government and private health insurance programs in which patients and providers are participating, each with its own set of complex rules and regulations, the burden to assure compliance with the rules of the programs has become enormous. The enhanced enforcement effort of both the government and private insurance payors has generated still greater pressure on providers. In fiscal year 2000, the United States Department of Justice reported $1.5 million in civil fraud recoveries, of which $840 million was in connection with health care fraud cases. The government has numerous legal weapons that it may apply to its health care fraud and abuse offensive. These include civil, criminal, and administrative sanctions.

False Claims Acts

(1) The Criminal False Claims Act makes it a felony to knowingly make or cause to be made any "false statement or representation of material fact in any application for any benefit or payment under a Federal health care program," including requests for reimbursement from any federally-funded health care program. Penalties for violation of the Criminal False Claims Act include a term of imprisonment of up to five years per violation, fines up to $25,000 per violation, and exclusion from federally funded health care programs. When excluded, an individual or entity can no longer provide services covered by the federally funded health care programs.

(2) The Civil False Claims Act imposes civil liability where a person or entity knowingly submits (or causes to be submitted) a false or fraudulent claim for payment to the federal government from any federally-funded health care program. The Civil False Claims Act also

prohibits knowingly using a false record to get a false claim paid, conspiring to get a false claim paid, and knowingly making or using a false record to avoid an existing obligation to pay the federal government. Penalties for violation of the Federal Civil False Claims Act include treble damages, fines of $5,500 to $11,000 per claim, and possible exclusion from federally-funded health care programs. Many states have enacted laws similar to the federal statutes that are not limited to the federal programs.

The Civil False Claims Act is the enforcement tool most commonly used by the federal government in the area of health care fraud and abuse enforcement. Potential False Claims Act issues include billing for medically unnecessary services, services not provided, or non-covered services; upcoding;[1] and duplicate billing, among others. Unfortunately, the potential for False Claims Act exposure in the area of physician services is serious, despite the fact that the vast majority of practitioners are acting in good faith.

Risk Areas

Billing for non-covered services is a major focus of False Claims Act liability that can expose urologists to serious consequences. Various clinical laboratory services, such as urinalyses or panel testings, based on "rule out" referrals or in the absence of a sign, symptom, condition, or diagnosis supporting the medical necessity of a service (as reflected in a carrier or intermediary local medical review policy) can create False Claims Act exposure. This is a function of the fact that the Medicare program does not typically pay for "routine" or "screening" services.

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[1] Upcoding means billing for a more complex or higher level service than that either performed or documented.

Similarly, although many providers submit services requiring pre-certification,[2] even when a pre-certification has not been obtained, some payors, including some Medicare and Medicaid managed care plans, take the position that such submissions are improper as the absence of a pre-certification necessarily means that the service is not covered.

Billing for medically unnecessary services is another significant source of potential exposure under the False Claims Act for urologists and others. For example, some carriers, by Local Medical Review Policy, will deny as medically unnecessary the use of certain, more costly LHRH analogs for the treatment of prostate cancer.[3] Urologists, like other health care providers, often incorrectly assume that the medical necessity for the services that they provide can and should be inferred from the medical record. Although it is true that Medicare auditors are obligated to give all reasonable inferences that come from a review of the medical record, including inferences regarding the reason why a procedure was performed, Medicare auditors typically do not make the same inferences that a practicing urologist would make. Because Medicare auditors often have limited, if any, medical training, they often do not correctly interpret medical records. Accordingly, medical records that fail to specifically state why services were ordered, where the medical necessity of that service is not easily inferred, create regulatory risk.

Basic legibility problems also continue to create exposure for urologists and other providers. A Medicare auditor cannot confirm the medical necessity of a service or the extent of the service from a visit or progress note that the auditor cannot read. Unfortunately, False Claims Act exposure can be as simple as that.

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[2] Pre-certification means that the payor, typically a managed care entity, will require that it approves a service in advance of the provision of the service as a condition of payment or coverage.

[3] Use of a diagnostic prostatic ultrasound for certain asymptomatic patients may also be viewed as a screening service.

Miscoded services are another very important source of False Claims Act liability for urologists. Reliance on outdated and incorrect "cheat sheets" and untrained front desk personnel to select procedure and diagnosis codes often leads to miscoding problems. It is critical for individuals with coding responsibilities to remain abreast of changes that may occur in the CPT and ICD-9 codes by receiving internal and external training, reviewing carrier bulletins and other payor instructions, and CPT and ICD-9 descriptor revisions or additions. Urology practices need to have "fail-safe" systems in place, such as monitoring and audit mechanisms, to ensure that coding and billing issues are "double-checked" frequently enough that problems are identified and addressed in a timely manner.

The submission of duplicate bills is also a significant potential source of exposure for urologists. Duplicate bills are often submitted to third party payors under the mistaken belief that the original claim has been lost or misplaced. The potential for False Claims Act and other liability increases when an organization has no system in place to identify and refund duplicate payments. Under the False Claims Act and a criminal law provision found in the Social Security Act, providers have an affirmative obligation to refund or disclose known overpayments involving the federal government. State law often imposes a similar obligation covering other health care overpayments.

Another potential source of False Claims Act liability exists as a consequence of the National Correct Coding Initiative ("NCCI"). The NCCI, a Part B Medicare payment restriction, specifies that certain less comprehensive services may not be billed to Medicare in addition to or instead of various more comprehensive procedure codes. Other NCCI edits prevent the billing for mutually exclusive services on the same date of service.

Certain urology codes, particularly procedures involving cystourethroscopy, are subject to these bundling edits. Unfortunately, some urologists do not have a system in place to screen for NCCI restrictions. The result of this lapse in compliance procedures is that "fragmented" or "unbundled" services are billed to Medicare. In some cases, the federal government has argued that a claim submitted to the Medicare program in violation of the NCCI constitutes a false claim, even if the claim was not paid.

Government attorneys and whistleblowers' counsel also are attempting to extend liability under the False Claims Act to violations of other statutory provisions using a theory of "implied warranty." According to this theory, when a provider submits a claim for reimbursement, he is making a representation that the service was provided in accordance with all applicable laws and regulations.

Failure to provide sufficient documentation supporting the medical services provided also may create False Claims Act issues. Surgical services, such as prostate biopsies or other procedures, are particularly vulnerable to this omission. Some urologists elect to document their work on a standard diagram, rather than with a dictated operative note. While not inherently problematic, the use of standardized diagrams without dictated notes may result in insufficient documentation to support the actual services performed.

The failure of urologists and other providers to meet the demanding documentation requirements of either the 1995 Evaluation and Management ("E&M") or the 1997 E&M Guidelines can also lead to False Claims Act exposure. Failure to (1) meet the history requirements, including the social history elements, and to specify sufficient detail in documenting the history of the present illness, (2) document the required numbers of systems in a review of systems, or (3) adequately reflect the complexity of the medical decision-making are

common concerns. Similar issues have created exposure in connection with consultation services. The Medicare program is actually engaged at present in assessing the adequacy of the documentation of "level 4" E&M and consultation services.

Another source of False Claims Act liability is office services provided by non-physicians that do not comply with the Medicare incident-to requirements. Certain services, such as administration of hormone or chemotherapy injections, may be billed as physician services, if they are provided by an employee of the physician, the physician is present in the office suite where the service is provided, and the other facets of the incident-to billing rules are met, including that the services are incidental to the physician's on-going care of the patient. Lack of appropriate physician presence can create False Claims Act exposure and has been the basis for a number of recent government False Claims Act settlements.

Anti-Kickback Laws

The Federal Anti-Kickback Law is a broad prohibition on the offer or receipt of anything of value (direct or indirect, overt or covert, in cash or in kind) which is intended to induce the referral of a patient for an item or service that is reimbursed under a federal health care program, including Medicare and Medicaid. Many states have enacted similar state prohibitions that apply to all payors, not just government programs. Violations of the federal law are punishable by a term of imprisonment not to exceed five years, trebled damages, civil monetary penalties of up to $50,000 for each violation, and exclusion from federally-funded health care programs.

In order to prevent application of the law to legitimate business relationships, a number of exceptions to the Federal Anti-Kickback Law have been created. These are commonly known as "safe harbors," and include protections for payments resulting from certain investments (including ownership in ambulatory surgery centers), payments for rentals of space and equipment, payments to *bona fide* employees, payments under contracts for personal services,

payments relating to physician referral services, payment relating to the purchase and sale of physician practices, remuneration paid pursuant to warranties and in the form of discounts, remuneration to group purchasing organizations, and certain arrangements with preferred providers and in Medicare/Medicaid managed care arrangements. Each of these safe harbors have specific requirements that must be met if the safe harbor is to apply. Although failure to comply with a safe harbor does not necessarily mean that a violation of the statute has occurred, compliance with a safe harbor is always the best practice.

Many common business arrangements have the potential to violate state or federal anti-kickback laws. Urologists should not have any arrangements with ambulatory surgery centers, hospitals, urodynamics centers, billing companies or others that may provide any form of payment or remuneration for referrals of patients for services that may be covered by a federally funded health care program, unless the arrangement falls squarely and appropriately within one of the anti-kickback law safe harbors or is otherwise permissible under the anti-kickback law. The Office of the Inspector General for the Department of Health and Human Services has issued guidance suggesting that providers involved in financial relationships which could create issues under the anti-kickback law should secure legal advice about those relationships.

Today, many urologists have ownership interests in ambulatory surgery centers. A new safe harbor protects these interests under certain circumstances. The safe harbors may be reviewed at the following website: http://oig.hhs.gov/ak/getdoc1.pdf. Ownership interests offered to a surgeon for little or no financial investment, or to encourage utilization of the facility, may violate the statute. Similarly, the government may perceive investment interests offered to non-surgeons or non-physicians as an effort to inappropriately reward or encourage increased referrals to the facility.

Ownership in companies furnishing lithotripsy services also is becoming increasing popular for urologists and may pose risks under the Federal Anti-Kickback Law. These lithotripsy companies sometimes contract with hospitals and ambulatory surgery centers to which the urologists make referrals. To minimize the risk of a kickback allegation, these contracts should reflect fair market value in an arms length transaction without considering any referrals or other business that might occur between the parties. In what is called an "under arrangements" relationship, in which the hospital bills Medicare for the service sub-contracted to the lithotripsy company, the government may evaluate fair market value of leased lithotripsy equipment by comparing the difference between the rate charged by the lithotripsy company to the hospital with that charged by the lithotriptor manufacturer to the lithotripsy company.

Urologists also should be cautious about relationships that may develop with pharmaceutical manufacturers from which urologists purchase drugs that are reimbursed by federally-funded programs. Prosecutors have recently taken actions against urologists who allegedly received free oncology drugs and other things of value, including money or free trips, as an inducement to switch patients from one medication to another. Prosecutors also have negatively viewed arrangements in which urologists are offered the right to purchase pharmaceuticals at significantly discounted prices. Incentives intended to encourage product selection based upon profit margins, rather than clinical criteria, have been scrutinized by the government. Although some of these areas of inquiry may be legally flawed, it is critical that urologists receive legal advice in connection with these kinds of issues.

Other possibly suspect arrangements under the Federal Anti-Kickback Law may include the following:

- hospital, ambulatory surgery center or other medical directorships where services are provided for compensation that is more than fair market value;
- providing less than fair market value payment to an ambulatory surgery center as compensation for performance of a procedure not on the Medicare list of ASC-covered procedures;
- waiving Medicare or Medicaid co-payments or deductibles without establishing the patient's good faith financial need or making reasonable efforts to collect the fees;
- discounts for the purchases of goods or services or for the sale of goods or services that are not based upon prompt payment or other appropriate bases;
- space lease arrangements that are not based fair market value;
- compensation arrangements, including free supplies, from medical equipment suppliers and other vendors whose products are used by the provider;
- compensation arrangements with physicians or other practitioners that are based upon the volume or value of referrals;
- certain marketing practices involving referral sources, including expensive meals, or tickets to entertainment or sporting events; and
- contracts with management service organizations or billing companies owned or controlled by persons or entities in a referral relationship, where the contracts do not reflect fair market value.

Self-Referral Laws

The Federal Self-Referral Law, commonly known as the "Stark law," prohibits a physician from making referrals for certain "designated health services" when those services are (1) furnished by an entity with which the physician has a direct or indirect financial relationship, and (2) reimbursed by Medicare or Medicaid. Many states have enacted similar state provisions. Intent is not an issue under the Stark law.

The designated health services covered by the federal law include inpatient and outpatient hospital services, clinical laboratory services, radiology and ultrasound services and radiation therapy services and supplies, and outpatient prescription drugs. Services payable under the ASC composite rate by the Medicare program are not designated health services within the meaning of the statute. Violations of the statute are punishable by civil money penalties of up to $15,000 per claim, the forfeiture of amounts paid for tainted services, and exclusion from federally-funded health care programs.

Like the Federal Anti-Kickback Law, several exceptions to the Stark law have been added by statute and regulation, including physician services, in-office ancillary services, certain Medicare/Medicaid managed care arrangements, investments in publicly traded companies and mutual funds, ownership arrangements involving hospitals and rural providers, payments for rental of equipment and space, payments in connection with *bona fide* employment arrangements, payments in connection with personal service arrangements, payments in connection with physician incentive plans and physician recruitment, certain isolated transactions, certain group practice arrangements, and payments by physicians for items or services at fair market value. Each exception has specific requirements that must be fully and completely met if the exception is to apply. If the Stark law were to otherwise prohibit a referral, an exception must apply or the statute will be violated.

Urologist ownership of companies that furnish lithotripsy services to hospitals may create self-referral problems when the urologist-owner refers patients to the hospital. One requirement of the applicable Stark Law exception is that the contract must be for fair market value. Although a portion of the final regulations implementing "Stark II" were recently published, they did not address all the requirements that these contracts must satisfy. Consequently, urologists

should remain attentive to new developments in this area and reassess their contractual relationships, as appropriate.

Other relationships that can create self-referral problems for urologists include practice compensation programs that reward shareholders or employee physicians based on orders of designated health services (such as clinical laboratory or ultrasound services); ownership interests in or medical director agreements with a hospital; part-time employment or independent contractor agreements; free or discounted space or equipment leases; and marketing agreements with entities owned by physician or hospital investors that do not reflect fair market value payments for necessary services.

General Fraud Statutes

It is a federal crime to use the mail, telephone, or other interstate wire services to further a scheme to defraud or to obtain money or property by false pretenses. Sanctions for violation of the federal mail and wire fraud laws include fines of at least $250,000 and imprisonment of five years. The submission of a false claim by mail or electronically will support a prosecution for mail or wire fraud.

The Health Insurance Portability and Accountability Act of 1996 created the new crime of health care fraud. This law prohibits any activity undertaken to defraud a health care program. It is important to note that violations of the law are not limited to efforts directed at government payers. Rather, the law applies to all payers. While prosecutors are still becoming familiar with this new statute, providers should expect increasing numbers of enforcement actions.

State Laws

Urologists also should be aware of the particular laws of the state(s) in which they operate. Many states have false claims acts, self-referral laws, anti-kickback laws, and general

fraud laws that are similar, or even more restrictive than the federal laws that we have already discussed.

Risk Avoidance

While there is no magic formula to ensure protection from government or private payor enforcement activities, the single best step that can be taken that will enable a urologist to minimize his or her exposure is the development of a health care fraud and abuse compliance program. Compliance programs have already become standard for large providers of health care. National suppliers and national chains of institutional providers of care have developed compliance programs for a number of years. Within the last few years, many physician practices have been developing compliance programs. Urologists and their group practices would be wise to commit to compliance programs as a means for preventing, quickly detecting, and correcting errors that could subject them to substantial, far-reaching sanctions.

WHAT IS A COMPLIANCE PROGRAM?

A compliance program is a series of internal controls that promote the prevention, detection, and resolution of conduct that may violate applicable laws, regulations, rules, or payor policies. Compliance programs establish mechanisms for addressing questions about appropriate behavior, as well as investigating and correcting inappropriate activities. Since the effectiveness of the program is dependent upon the understanding, cooperation, and commitment of all physicians, employees and other personnel involved with the practice, a compliance program also establishes procedures for training about appropriate standards, imposing discipline when the standards are violated, and reducing the risk of similar problems recurring in the future.

A compliance program requires a urology practice and its individual members to commit themselves and their resources in an appropriate fashion and at an appropriate level in order to assure compliance with applicable rules and regulations -- instead of waiting for the government

or an outside entity to identify problems and impose sanctions. While there will necessarily be a number of elements common to all compliance programs, the design structure and operation of each program will depend upon and should reflect the culture of the particular organization and must be tailored to address that organization's size, structure, resources, and needs.

WHAT A COMPLIANCE PROGRAM IS NOT

A compliance program is not a guarantee of absolute protection from the risks inherent to participating in government and private insurance payment programs. Even the most effective compliance program may not be able to avoid the imposition of some form of sanctions. Further, a compliance program is not a document that can be left on the shelf and be forgotten. To be effective, a compliance program must become an element in the everyday operations of the organization, growing and changing with the practice, and adapting to new developments.

WHY SHOULD A UROLOGY PRACTICE ADOPT A COMPLIANCE PROGRAM?

The impetus for the adoption of compliance programs comes from the Federal Sentencing Commission Guidelines, a series of provisions designed to assure consistency in the imposition of sanctions in criminal cases. Under the Sentencing Guidelines, when an entity is sentenced as a result of a criminal conviction, the existence of an effective compliance program is considered **a primary mitigating factor that can reduce the criminal penalty imposed**. At one time, compliance programs were largely unknown in the health care industry. With the explosive increase in health care enforcement cases, however, the significance and relevance of compliance programs has become evident.

The major catalyst for development of compliance plans in the health care industry occurred in 1994 as a result of the settlement between National Medical Enterprises ("NME") and the United States. In addition to agreeing to pay $379 million to settle allegations of false claims and kickbacks, NME agreed to adopt a corporate integrity agreement that included a

government imposed compliance program developed in coordination with the U.S. Department of Justice and the Office of the Inspector General of the Department of Health and Human Services ("OIG"). Since the resolution of the NME case, virtually every settlement between the government and a major provider of health care services has resulted in the imposition of a compliance program under the terms of a corporate integrity agreement, which allows the provider to remain a participant in government-funded health care programs. The government has come to impose corporate compliance programs on small providers and physician practices in concluding settlements with them, as well.

The pressure to implement a compliance program will continue to increase. The OIG committed to develop model compliance programs for various facets of the health care industry. OIG has published model programs for clinical laboratories, hospitals, home health agencies, hospices, billing companies,[4] nursing homes, durable medical equipment suppliers, Medicare + Choice organizations, and individual and small group physician practices. The model plans are available on the OIG's website, at www.hhs.gov/progorg/oig.

On December 24, 1997, the OIG published a notice in the Federal Register (62 Fed. Reg. 67392) outlining the criteria it will apply in determining whether to exclude from Medicare, Medicaid, and other federal health care programs a provider found to have violated program rules. **The adoption and operation of an effective compliance program were listed as key factors that the OIG will use in making this evaluation.**

Under the Health Insurance Portability and Accountability Act of 1996, the federal government gave the OIG the power to exclude managerial employees, officers, and owners of health care entities where the entity is found responsible for certain acts of health care fraud and

[4] Because physicians like urologists, have a billing function, the model compliance plan for billing companies provides some useful guidance. OIG has stated that large physician practices should combine the small group physician practice and the billing company guidance.

abuse, even where the managerial employees, officers and owners did not know of, direct, benefit from, or countenance the entity's wrong-doing. Where potential "strict liability" exists for managerial employees and officers, owners are subject to exclusion on only the slightly higher standard that they failed to prevent the entity's wrong-doing through reckless indifference. The government might consider the absence of a compliance program as evidence of reckless indifference. In an environment like this, where an entity's misconduct can have long-term adverse professional repercussions for all personnel affiliated with it, an effective compliance program becomes even more important.

Finally, urologists should establish compliance programs because it makes good business sense. As noted above, the complexity of participating in the variety of government and private insurance programs has imposed an extraordinary burden on providers, and the potential for error is significant. While urologists are clearly committed to following the rules, government and private enforcement authorities are becoming intolerant of errors and wield tremendous power to impose sanctions. While not foolproof, a compliance program is the most effective way to reduce the likelihood that the occasional mistake will evolve into a pattern of inappropriate behavior inviting outside scrutiny and possible sanctions. **The federal government has stated repeatedly that the voluntary adoption of an effective compliance program is the single most important step that health care providers are likely to be able to take to (1) reduce the risk of a criminal charge and (2) reduce any civil fines or penalties.**

ELEMENTS OF A COMPLIANCE PROGRAM FOR A UROLOGY PRACTICE

Under the Federal Sentencing Commission Guidelines, an effective compliance program should reflect the following seven elements, although the OIG's Compliance Program Guidance for Individual and Small Group Physician Practices suggests a more limited approach may be undertaken, depending on the practice's size, resources, and other factors. These requirements are listed in the OIG guidance in different order and described in slightly different terms, but the requirements are still basically the same.

1. **Written standards of conduct.** The provider should adopt a set of guidelines, as well as policies and procedures, to be followed by all personnel associated with the organization. These guidelines should reflect the organization's commitment to compliance in general, as well as address specific areas of concern for that organization. The standards of conduct should be more detailed if the organization does not already have a separate, more extensive policy and procedures manual.

2. **Designation of compliance officer contact or committee.** The organization should identify an individual or group of individuals responsible for the operation and monitoring of the compliance program. These individuals should report directly to the governing body (such as a board of directors) or other ultimate decision-makers within the practice.

3. **Education and training for personnel in the organization.** The organization must ensure that all practice personnel are educated and periodically retrained on an on-going basis about the existence of the compliance program, the written standards of conduct, and the rules and regulations with which the practice must comply. Individuals with billing and coding responsibilities should undergo additional internal and external training specific to their duties.

4. **Effective mechanism for communication.** The practice should establish a reporting mechanism, through a suggestion box, e-mail system or other process, by which an employee (or others) may raise questions or complaints without fear of any retaliation. Telephone hotlines are sometimes used for this purpose in larger practices. The compliance officer or compliance committee should also be able to communicate with and disseminate information to all practice personnel.

5. **Internal investigation and disciplinary process.** The practice should develop a process to investigate allegations of impropriety and to discipline individuals who have acted inappropriately.

6. **Periodic auditing and monitoring.** The practice should have a mechanism for performing periodic auditing and monitoring of its operation to assure compliance with applicable rules and regulations.

7. **Establishment of response mechanism.** The practice should develop a mechanism for responding to and correcting identified problems. It should develop a process for screening its personnel and job applicants to prevent delegating authority to individuals who may have a propensity to engage in illegal activity. In essence, this is a kind of "credentialing" process.

Commitment and training

Compliance programs require commitment from all individuals in a practice. After the compliance program has been established, personnel should be informed about its existence and how it operates in an organized, thoughtfully designed training program. In the initial training that occurs under the compliance program, personnel should also be educated about the fraud and abuse laws and regulations that affect the organization, as well as the corrected policies and

procedures implemented based on issues identified in the baseline audit. New employees should be trained as part of their orientation. Although live sessions are generally much more productive than written materials, practices must design their training programs to meet the restrictions imposed by limited resources. Many suggest that at least annual training sessions and refresher courses should be conducted regarding the Standards of Conduct and the requirements of the Compliance Plan, as consistent with any resource limitations.

An effective compliance program is a dynamic process that requires regular re-evaluation. Every organization should periodically assess the success of its initial program and revise any Standard of Conduct, procedure or policy, as appropriate.

The discussion and materials contained here are only intended to be a starting point from which a practice builds a program that reflects the practice's philosophy and needs. A generic program that is never implemented in a good faith and energetic fashion will have no value and will be perceived by the government and other third parties as merely demonstrating apathy or worse, rather than a real commitment to compliance.

A model set of standards of conduct and a model compliance plan, which together constitute a model compliance program, appear on the following pages. **The user should insert the appropriate identification information and fill in the numerical blanks and otherwise adapt the model to its particular needs, payer relationships, and the like.**

STANDARDS OF CONDUCT[5]

, is dedicated to furnishing high quality urological diagnostic and therapeutic services in accordance with all pertinent federal and state laws. The Practice will take reasonable steps to ensure that it and its staff acts in conformity with pertinent laws and regulations. The term "affiliates," as used in this document, means the Practice's physicians or other practitioners, suppliers, vendors, independent contractors, and others, with whom the Practice has an active relationship. The following are the Standards of Conduct that the Practice has adopted and which are binding on the Practice, its employees, and its affiliates:

General Matters

1. All employees of the Practice and its affiliates must cooperate fully and completely with any compliance program or initiative instituted by the Practice, as they may be amended from time to time.

2. All employees of the Practice and its affiliates must endeavor to fully and completely comply with the Practice's policies and procedures.

3. Employees and affiliates must immediately report violations or suspected violations of the compliance program, these Standards or the Practice policies and procedures to the Compliance Officer or another member of the Compliance Committee.[6] The Practice will investigate reports promptly, as appropriate under the circumstances.

4. All treatment recommended and provided by the Practice will be medically necessary or will be provided and billed for as screening, routine, or preventative services in compliance with the payor's applicable rules and requirements.

5. The Practice, its employees, and its affiliates, when acting in connection with Practice patients, will not over-utilize services or under-utilize services.

6. The Practice, its employees, and its affiliates will not directly or indirectly pay (in cash or in kind) any person or any entity for patient referrals or for arranging for the purchase or lease of any item or service in violation of state of federal law. The Practice, its employees, and its affiliates will not directly or indirectly receive from any person or any entity any payment (in cash or in kind) for patient referrals or for arranging for the purchase or lease of any item or service in violation of state of federal law. Except for certain exceptions, it is illegal or unethical to offer or solicit any financial inducement,

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[5] Please note that some of these suggested standards are merely reflective of what the authors believe to be best practices, while others are required by law.

[6] Depending on your organization's size and needs, your organization might elect not to have a Compliance Committee. This model plan is written under the assumption that both a Compliance Officer and a Compliance Committee will be selected.

gift or other thing of value to prospective patients or others in order to encourage patients to be treated by the Practice.

7. The Practice shall not refer patients to entities with which the Practice, its employees, or any affiliates have an ownership or other financial interest, except as permitted by the Federal Self-Referral Law and any other applicable restrictions on self-referrals. Employees and affiliates are obligated to inform the Compliance Officer promptly of financial or other interests that they have with any person or entity with which the Practice does business, pursuant to the conflict of interest standard that appears below.

8. The Practice shall not enter into a financial relationship with a referral source or any other person in a position to make referrals unless the payments or other financial terms reflect fair market value in an arm's length transaction without regard to any referrals or other business generated between the parties. To the extent feasible, the Practice shall use objective data in assessing fair market value.

9. Except for the occasional modest expressions of gratitude from patients or items of nominal value, the Practice and its employees should refuse gifts, loans, tickets, meals or anything of value offered by outside individuals or companies, including the Practice's affiliates, unless receipt of the thing of value has been disclosed to the Compliance Officer, and the Compliance Officer believes that the receipt of the gift, loan, or other thing of value will not create any regulatory violation or potential conflict of interest.

Quality of Care

1. All patients shall be treated with respect and dignity.

2. The Practice shall provide quality care at a medically appropriate level and without regard to race, color, religion, and national origin.

3. The Practice shall make no distinction in the care provided based on ability to pay except as medically, legally, and ethically appropriate. Each patient, no matter what the payment source or level of reimbursement, shall be provided with a high level of superior care and cost-effective treatment.

4. Informed consent shall be obtained for all treatment, as appropriate and required under the circumstances.

5. Patients and their representatives will be accorded appropriate confidentiality, privacy, counseling and opportunities for resolution of complaints.

6. All Practice personnel and affiliates will be licensed, credentialed and skilled at the services they perform, as appropriate and as required by law.

7. The Practice will comply with all laws and regulations regarding patient rights and privacy.

8. Patient telephone inquiries shall be referred to an appropriate person in a timely manner. The inquiry and the response given will be documented in the patient's chart.

9. On a periodic basis, the Practice, through its Compliance Committee, will review and evaluate its procedures, standards and treatment results to ensure that its care remains of superior quality.

Records and Other Property

1. The Practice records and documents are of a highly confidential nature. Except as required or authorized by law, they shall not be disclosed to or discussed with anyone not employed by or affiliated with the Practice without the written permission of the Practice or the written authorization of the relevant patient or patient representative, as appropriate. Employees and affiliates shall take reasonable precautions to ensure that their conversations and other communications safeguard patient confidentiality.

2. No property belonging to the Practice may be removed from a Practice location without the permission of the Practice Administrator.

3. Except as expressly permitted in writing, by the Practice, no employee or affiliate may use or disclose to any person any trade secrets or other confidential or proprietary information belonging to the Practice, including, but not limited to, records and files, patient lists, referral information, marketing materials, business records, financial documents, and any other papers, records, and documents the disclosure of which might adversely affect the Practice or its patients.

4. Upon separation, no employee or affiliate may take or retain any of the Practice's papers, patient lists, fee books, patient records, files, or other documents. Copies of any such materials may only be taken or retained as specifically authorized as part of a written separation agreement.

5. No edits should be made to clinical records unless the edit is properly undertaken in accordance with state law and relevant professional ethics. Where edits are made after the date of the original entry, the reason or the basis for the edit should be documented.

6. It shall be the responsibility of the Compliance Officer, or his or her designee, to ensure that all provider agreements, provider manuals, and provider billing and coding instructions and bulletins are maintained in centralized, well-organized manner. The Compliance Officer shall coordinate with the billing personnel and clinicians to ensure that information is shared appropriately with all personnel who should have access to that information.

Certain Reporting, Survey, and Other Requirements

1. All employees and affiliates shall immediately report to the Practice any contact, inquiry, investigation, proceeding, charge, or complaint involving any court of law, administrative tribunal, or state or federal agency that is related to the Practice or its operations in any manner.

2. Any employee or affiliate of the Practice must immediately notify the Compliance Officer in writing if he or she becomes the subject of or there is presently pending against him or her any request for information, inquiry, investigation, or proceeding, the outcome of which could result in the suspension or revocation of his or her licensure, any professional membership or certification. Thereafter, any such employee or affiliate must keep the Practice informed of the progress and outcome or resolution of such request, inquiry, investigation, or proceeding in a timely and complete fashion.

3. Any employee of the Practice or affiliate must immediately notify the Practice if he or she is excluded, suspended, debarred, or removed, whether voluntarily or involuntarily, from any government or commercial payor plan or program.

4. On an annual basis, each employee will fully and accurately complete a compliance questionnaire like the one attached to this document as Exhibit 1. It shall be the responsibility of the Compliance Officer, or his or her designee, to ensure that these questionnaires are distributed and completed in accordance with this policy.

5. Where feasible, upon separation, an employee shall be asked to participate in an exit interview and provide complete and accurate information to the Practice in connection with that interview. The exit interview will include the completion of a questionnaire form like the one attached to this document as Exhibit 2. The exit interview shall be conducted by the Compliance Officer, or his or her designee.

Governmental and Other Inquiries or Communications

1. The Practice will respond truthfully to any governmental inquiries as required by law.

2. The Practice will provide accurate information in responding to any governmental, payor, or patient inquiries.

3. During a government investigation, no person shall conceal, destroy, or alter documents; knowingly make any false statements to the government's representatives; or attempt to cause another person to fail to provide accurate information or obstruct the inquiry.

4. Every contact with a payor or a governmental agency in which the Practice orally receives significant coverage or other advice that the Practice intends to rely upon in submitting claims or taking other action, particularly on a recurring basis, should be documented using a written communication like the one found at Exhibit 3, which shall be completed and filed in an appropriate, centralized location at the Practice, for which the Compliance Officer will be responsible.

Maintenance of Compliance Plan Documents

1. A bound copy of the current Standards of Conduct and Compliance Plan document shall be maintained in a readily accessible and well publicized location at all times. A copy of these documents shall be provided to each employee at the time of implementation of the compliance program or on their date of hire for employees hired after the initial date of implementation.

2. It is the responsibility of the Compliance Officer to audit compliance with this requirement at least once each year.

Screening Obligation

1. On an annual basis, the Compliance Officer, or his or her designee, will check the Lists of Excluded Persons maintained by the Office of the Inspector General to the Department of Health and Human Services and the General Services Administration to ensure that no employee or affiliate is excluded from any federal programs.[7]

2. The HHS/OIG List of Excluded Individuals/Entities may be found at http://www.hhs.gov/oig.

3. The General Services Administration List of Parties Debarred from Federal Programs may be found at http://www.arnet.gov/epls.

4. These lists shall also be queried any time that a new employee or significant affiliate is selected.

Billing--
General Matters

1. The Practice will take reasonable steps to ensure that claims for reimbursement are accurate and complete, including periodic pre-submission audits of claims against supporting medical record documentation.

2. Claim forms will be submitted in a timely manner taking all reasonable steps to ensure the accuracy of the date of service, the nature of the service, the persons or entities who provided the service, and all other information, including the signatures used.

3. The Practice, employees, and affiliates will select the most appropriate CPT codes, ICD-9 codes, and modifiers in describing services performed, regardless of the impact upon payment.

4. Order forms, billing instruction sheets, and other forms will not be designed in any way that inappropriately steers practitioners towards higher level procedure codes or diagnoses codes that will support third party payor coverage.

5. The Practice shall take reasonable steps to ensure that services are documented appropriately as required by the applicable billing and coding requirements.

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[7] The Health Insurance Portability and Accountability Act of 1996 effectively imposes this obligation on health care providers. A person or entity who has been "exclud ed" from the federally-funded health care programs may not bill those programs, directly or indirectly, for services covered by those programs. Because of resource limitations some providers choose to limit the screening of affiliates to affiliates with substantial relationships with the entity. If an excluded employee or contractor is not identified in a screening program, civil monetary penalties could be imposed by the federal government.

6. The Practice shall take reasonable efforts to ensure that the federally funded health care programs and other payors are not billed inappropriately for routine or screening services for which they do not provide coverage.

7. If the Practice intends to bill for a Medicare service that is likely to be denied as not reasonable and necessary (i.e. not medically necessary), the patient shall be informed and shall complete an advance beneficiary notice form (also known as waiver of liability form) before the service is provided. The form shall state why this specific service is likely to be denied on the basis of medical necessity and that the patient will be financially responsible for the service. The patient may be billed for the service after Medicare has denied payment. It is not appropriate to use advance beneficiary notice forms for all or substantially all uses of a particular type of service. Advance beneficiary notices need not be used where a service is always, or virtually always, not covered by Medicare.

8. Except in connection with coordination of benefits, duplicate bills shall not be submitted to a third party payor unless marked as a "duplicate" or until such time as the payor has indicated that the prior bill is lost or otherwise unavailable. The third party payor's statements regarding the status of the prior bill should be documented and maintained.

9. The Practice shall not provide out-of-network services in a PPO, HMO, or other plan at in-network fees if such discount is not permitted under applicable federal or state law. To the extent that such discounts are given, the discounts shall be listed on the claim forms for the services or otherwise disclosed in writing to the applicable payor.

10. Claims for services, items, and for the administration of drugs shall not be issued until the service, item or drug is actually provided or dispensed.

11. No payment shall be sought for pharmaceuticals provided to the Practice as a free sample not intended for resale.

12. Claims to third party payors shall not be submitted for missed appointments unless the applicable payor reimburses for such services.

Assignment Issues

1. If any Practice employee or affiliate receives any fees or charges for services performed during his or her employment by or affiliation with the Practice that are Practice services, the employee or affiliate shall remit such payment to the Practice promptly.

2. The Practice shall obtain patient written consent to bill and collect for services on an assigned basis before the Practice bills any third party payors for such services.

3. It shall be the responsibility of the check-in or admissions personnel to verify the presence of such a consent in the patient's medical record at the time of each patient visit or service.

Local Medical Review Policies

1. Medicare and other carriers issue Local Medical Review Policies that restrict the ability of providers to bill certain services unless certain enumerated conditions, signs, symptoms, or diagnoses are present.

2. The Practice shall maintain accessible and well-publicized files or binders that include copies of all such Limited Medical Review Policies that are issued by payors and which are applicable to services or items offered by the Practice.

3. Unless the Practice disagrees in good faith with a particular Local Medical Review Policy and articulates a reasonable basis for that disagreement, it shall only bill such payor in accordance with the requirements of such policy.

4. Where the Practice disagrees in good faith with a Local Medical Review Policy of a payor, the Practice shall take steps to document in a communication with the applicable payor the nature and the reasons for the Practice's disagreement with the policy.

5. Under no circumstances will procedure or diagnosis codes be used that are not clinically accurate in an effort to circumvent any Local Medical Review Policy.

Evaluation and Management Services (E&M)

1. Persons involved in the process of documenting or selecting E&M services shall read and review the applicable sections of the CPT manual on an annual basis.

2. Practitioners shall use the full range of E&M codes, selecting the most appropriate level of service for each individual service based on the requirements for each level of service and the medical needs of the patient.

3. A level five E&M service shall only be billed where the requirements of a comprehensive history, a comprehensive examination, and medical decision making of high complexity are present, are necessary, were performed, and were appropriately documented.

4. A level five E&M service should reflect medical decision making of high complexity, meaning that an extensive number of diagnoses or management options are present, where there are extensive or complex data and other information reviewed, or where there is a high risk of complications and/or morbidity or mortality.

5. A level four E&M service shall only be billed where the requirements of a comprehensive history, a comprehensive examination, and medical decision making of moderate complexity are present, are necessary, were performed, and were appropriately documented.

6. In documenting reviews of systems, positive findings must be specified in sufficient detail and may not be documented with a notation of "positive" only.

7. In documenting reviews of systems, negative findings must be noted. They also must be explained where they are unexpected or unusual under the circumstances.

8. Time becomes the most significant factor in determining E&M services only when the time spent counseling the patient or family members or others predominates, meaning that such time accounts for more than half of the time spent providing services.

9. Where counseling times are used as the basis for the selection of an E&M service, the total counseling time and the total visit time shall be documented in the record.

10. Until such time as the Health Care Financing Administration acts, documentation of Medicare evaluation and management services shall meet the requirements of either the 1995 or 1997 guidelines.

Consultations

1. Consultations will be billed when appropriate.

2. Consultations must be requested by a physician or other practitioner. A consultation involves a request for advice or an opinion from one practitioner to the consultant.

3. The request for a consultation must be documented in the patient's medical record.

4. The report of a consultation must be sent to the physician or other practitioner requesting the service.

5. Consulting physicians shall order diagnostic services and provide treatment as appropriate.

6. Consulting physicians shall bill only for the appropriate level of consultation and as consistent with the applicable documentation standards.

7. Use of the terms "referring physician" or "referral" are not consistent with a request for a consultation. They imply that an E&M service, not a consultation service, is being provided.

Global Period Issues

1. The Practice will not bill separately for services performed within a global period unless those services are separately identifiable.

2. The -25 modifier shall only be used to designate a separately identifiable service.

Ancillary Provider Issues

1. Services of nurse practitioners, physician assistants, and certified nurse specialists may be billed in the name of these practitioners to the Medicare program when various requirements are met. <u>These services are commonly described as "incident to" the physician's services.</u>

2. Services performed by a nurse practitioner, physician assistant, or certified nurse specialist, among others, may be billed "incident to" a physician services (so long as no direct bill from the limited license practitioner is submitted).

3. All "incident to" services must be provided as an integral, though incidental, component of the physician's care of the patient under the direct supervision (as defined under HCFA guidelines) of a physician.

4. Direct supervision means that the physician must be present in the office suite and readily available to give advice and direction during the entire time that the "incident to" service is provided.

5. All "incident to" services shall be provided by personnel in accordance with any state law requirements or restrictions, including any limitations on the scopes of practice.

6. Direct billing of Medicare services in the name of the nurse practitioner, physician assistant, or certified nurse specialist is permitted where, among other requirements, no facility or other provider will claim reimbursement for the services provided. There are no limits on the locations where these direct-billed services may be provided.

7. Services billed directly to the Medicare program may be collected by an employer.

Use of Signature Stamps

1. Signature stamps will only be used where authorized by the practitioner involved.

2. Signature stamps will only be used by designated personnel, as provided for in a written policy issued by the Practice.

3. Signature stamps shall be maintained in a secure location and will be maintained in a locked location after hours.

Collection of Co-Payments and Deductibles and Refunds of Overpayments

1. It is the policy of the Practice to make a reasonable and good faith effort to collect any co-payment and/or deductible owed to it. Checkout personnel will be responsible for collecting co-payments and deductibles or the billing personnel shall be responsible for billing for those charges.

2. Co-payment or deductible obligations may be waived by the Practice if a good faith financial need for such a waiver is present. All waiver decisions will be appropriately documented in the patient's financial record and will show the basis for that decision. A simple income and expenses form completed by the patient will satisfy this requirement.

3. The Practice will refund any known overpayments that the Practice is not entitled to retain within ninety (90) days of the date that they are identified. If insurance carrier

policy requires a written notification of account overpayment prior to issuing a refund, the Practice will issue such notification within ninety (90) days.

Professional Courtesy

1. The Practice shall not provide or accept professional courtesy services to or from any person in a position to refer or to influence referrals.[8]

Conflicts of Interest and Related Matters

1. Employees and affiliates of the Practice shall report to the Compliance Officer any actual or potential conflict of interests that arise in connection with the Practice, including, but not limited to, any offers of incentive payments or free items or services offered by suppliers or vendors of the Practice. Potential conflicts may also arise due to demands of outside activities that may distract or hinder performance or cause use of the Practice resources for other than the Practice purposes.

2. Employees and affiliates shall cooperate with the Practice in resolving actual or potential conflicts of interests.

Contracting and Affiliation Obligations[9]

1. The Practice shall provide copies of its Compliance Program to all of its affiliates who are in any significant position to refer, who are in any significant position to induce referrals, who order substantial services from the Practice, or who are suppliers or vendors with whom the Practice does substantial business on an annual basis.

2. The Practice shall take reasonable steps to ensure that, on a prospective basis, all contracts or modifications to existing contracts with the affiliates listed above shall incorporate the Practice's compliance program by reference.

3. The Compliance Officer shall be responsible for ensuring that such affiliates receive any updated versions of the Compliance Plan.

Integrity of Financial Reporting and Funds Control

1. The Practice shall take steps to ensure that all assets and liabilities are accounted for properly, in compliance with all tax and financial reporting requirements, and in accordance with generally accepted accounting principles.

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[8] In the alternative, although the federal government has not definitively dealt with the issue of professional courtesy, some practices offer professional courtesy to all similarly situated professionals, without discriminating against persons not in a position to refer or influence referrals and without limiting professional courtesy to "insurance only" discounts. The OIG, in its Guidance for Individual and Small Group Practices. suggests that this is not inappropriate, although the guidance fails to analyze professional courtesy under the Stark Law. OIG indicated that it had severe reservations about professional courtesy consisting of "insurance only" arrangements. For this and other reasons, we recommend that "insurance only" billing not be employed.

[9] This provision, like others in the model, may prove too burdensome to some physician organizations. If so, a practice might want to limit this standard simply to any billing company used by the practice.

2. The Practice shall not permit assets, payments, or funds to be mischaracterized or misrepresented on its financial records.

Marketing

1. Any marketing and advertising activities used to educate the public, provide information to the community, increase awareness of services, and to recruit colleagues will present only truthful and non-deceptive information and will comply with state professional misconduct laws.

2. Claims made in marketing and advertising material that are capable of objective confirmation shall have a reasonable, documented basis.

3. Testimonies shall not be used if not permitted under the applicable state law or ethical prohibitions.

Integrity of Data Systems

1. The Practice will establish procedures for maintaining the integrity and security of all electronic data collection systems, including regular back-ups on disc, tape or other format, and regularly scheduled virus checks.

2. The Practice will develop procedures to prevent unauthorized access and disclosure of confidential electronic data in accordance with the federal security standard of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA").

Diagnostic Services

1. The Practice shall ensure that all Medicare or Medicaid diagnostic services are supported by an order from a treating physician. The order may either be in writing or oral. If the order is oral, it shall be recorded in the medical record by Practice personnel authorized to do.

2. Services shall not be billed to payors for screening services or on the basis of "rule out" diagnoses, unless the payors provide for coverage for such screening services.

3. The medical necessity of any diagnostic service must be determined and supported by the signs, symptoms, conditions, or diagnoses documented in the patient's medical record.

4. Standing orders for diagnostic testing service are not encouraged. If used, they should be in writing, carefully drafted to ensure that they reflect medical necessity, and reviewed on a periodic basis to ensure their continuing appropriateness.

5. Clinical laboratory panels shall be ordered only after considering the need for a panel and the relative cost of ordering alternative, individual tests.

6. If the Practice itself offers laboratory panels, the Compliance Officer shall at least annually ensure that the panels listed on its order forms reflect the current CPT codes and descriptors and that ordering practitioners are given written notice of the elements of the panel.

7. The Practice shall not order panels where individual tests can meet the clinical needs of patents at lower cost.

NCCI Bundling

1. The Practice shall take reasonable steps to review all Medicare claims before submission to determine if the National Correct Coding Initiative ("NCCI") payment edits would indicate that the claims should not be submitted. The NCCI edits are payment restrictions implemented by the Medicare program that are designed to prevent (1) the separate billing of codes that are components of comprehensive codes when the comprehensive codes are billed and (2) the billing of mutually exclusive services on the same date of service.

2. The Practice shall update its resource materials to familiarize itself with the quarterly changes to the NCCI edits.

3. The Compliance Officer shall include NCCI issues in the Practice's compliance training programs.

Compliance Reviews

1. The Practice's Compliance Officer will review 4 claims per physician every quarter prior to submission to ensure accurate procedure and diagnosis coding.

2. Practice physicians shall review the medical necessity and procedure and diagnosis coding for 4 claims for each physician every quarter.

3. Where any known overpayments are identified in these reviews or otherwise, the Practice shall make the necessary refunds.

4. Where any pattern of inappropriate or inaccurate codes or services are identified, the Compliance Officer shall counsel the individual involved regarding the appropriate standards.

5. Thereafter, the Compliance Officer shall review an appropriate number of claims and related documentation to monitor the individual's performance, until such time as the Compliance Officer considers the issue to be resolved.

Approved and Adopted This 25th Day of March , 2004

Signatures of Appropriate Practice Officers:

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_____

Each employee and affiliate of the Practice must recognize that he or she has assumed a number of responsibilities by joining the staff or affiliating with the Practice. This document describes the two principal elements of those responsibilities.

A. CONFORMITY WITH THE STANDARDS OF CONDUCT

First, each employee or affiliate is responsible for making sure his or her conduct is in conformity with the Standards of Conduct listed above, any other Practice policy, any third party payor requirements, and all applicable federal and state rules, regulations, and statutes.

If, at any time, you have a question as to whether a procedure or action is appropriate under the Standards, then you should contact the Compliance Officer,
If you do not feel comfortable discussing the situation with the Compliance Officer directly, you may anonymously report the issue by mailing a statement to the Practice Compliance Officer at . Concerns also may be reported to the members of the Practice's Compliance Committee. The Practice's Compliance Committee consists of as well as the Compliance Officer.

The Compliance Officer position was created so that any employee or affiliate who has a question about what was proper conduct could secure any needed information. The Compliance Officer will report to the Practice's Compliance Committee and to the ultimate authority within the Practice. The Compliance Officer, working with legal counsel, as needed, will be able to answer questions about the Standards of Conduct and resolve disputed interpretations. The Compliance Committee also can and will take whatever action is necessary to investigate a complaint and institute corrective action, whenever such action is required.

B. REPORTING VIOLATIONS OF THE STANDARDS OF CONDUCT

Second, it is the responsibility of each employee or affiliate to report any violations of the Standards of Conduct, any other Practice policy, any third party payor requirements, or any federal or state rule, regulation, or statute. A form that may be used to report such concerns is attached as Exhibit 4.

Issues may be raised anonymously by completing the report form attached. Because it is often difficult to explore issues raised anonymously (since the Compliance Committee cannot ask for additional information from an anonymous source), we prefer other types of reports of issues. If you decide to report an issue anonymously, please be as specific and detailed as you can possibly be so that the Compliance Officer and Compliance Committee can fully look into the issues you raise. Please give a detailed explanation of the issue, how long you believe it has been an issue, what documents or persons can help to further explain the issue or that reflect or are involved in the conduct, and what steps, if any, have been taken to resolve or investigate the issue.

The Practice shall maintain the anonymity of those raising issues subject to the limits imposed by law and as otherwise consistent with the purposes of the compliance program. No

retaliation or retribution will be tolerated against any person who raises a compliance concern in good faith.

* * *

The Standards of Conduct must be followed by all the Practice employees and affiliates. Any violation of the Standards is a serious matter. Employees and affiliates may be subject to discipline, up to and including termination, for violations of these Standards. The Practice's Standards of Conduct do not constitute an employment or other type of contract. You should not and may not interpret any of these Standards as a promise of continued employment or any other continued contractual or other relationship.

THE COMPLIANCE COMMITTEE

As indicated above, the Practice's Compliance Committee shall consist of and the Compliance Officer, If a Committee member is involved personally and directly in any allegation that is raised, he or she will abstain from any consideration of any such allegation. If all the Committee members are involved personally and directly in any allegation, the Practice's attorneys will be notified and informed of the nature of the allegation and shall be asked to undertake an appropriate investigation as warranted by the allegations.

A. INVESTIGATIVE PROTOCOL

A primary duty of the Compliance Officer shall be to facilitate reports of possible misconduct from the Practice's employees and affiliates. The Compliance Officer shall ensure that every report, whether written or oral, that is received shall be reviewed and evaluated. Reports will be forwarded to the Compliance Committee and to the Practice's attorneys, as necessary or appropriate, in the discretion of the Compliance Officer.

After consulting with the Practice's attorneys, the Compliance Officer and the Compliance Committee may determine that a report does not warrant further investigation. If the Compliance Officer and Committee conclude, based upon their initial review of a report, that further investigation is warranted, the Committee may ask the Compliance Officer or the Practice's attorneys to conduct the investigation, or the Compliance Committee may conduct the investigation itself. All investigations shall be completed in a timely fashion.

At the conclusion of any investigation, a report will be written to the Practice's attorneys, or, in the case of an investigation conducted by the Practice's attorneys, to the Compliance Committee, containing a summary of the reported allegation, the steps taken to investigate the report, the investigative findings, and the recommendations, if any, for corrective action. In consultation with the Practice's attorneys, the Compliance Committee shall act on all investigatory conclusions in a timely fashion. In the event the employee or affiliate who made the incident report chose not to remain anonymous, the findings will be reported back to the individual who originally made the report to the extent consistent with the functioning of the Compliance Plan and the other needs of the Practice. The results of the report will be used to plan remedial training to assure the chances of repeated incidents are reduced in the future.

B. AUDIT PROTOCOL

The Compliance Committee shall institute a plan for periodic internal audits of certain facets of the Practice's operations. The areas that shall be audited are billing practices and procedures, procedures relating to the adequacy of medical record documentation, utilization, and other matters. These audits shall be performed no less than semiannually. External chart audits by an independent, third party shall be conducted no less than annually. In addition, the Practice shall periodically assess its financial and other relationships with referral sources, other health care facilities, and pharmaceutical manufacturers and medical equipment suppliers.

C. COMPLIANCE TRAINING

As part of its compliance program, the Practice shall provide periodic training for its employees and, in its discretion, its affiliates. The focus of the training shall be the Standards of Conduct and the way in which the employee disciplinary system will be used to enforce the compliance program. Each employee and affiliate attending a program shall be required to sign an attendance sheet establishing attendance at each training session that is conducted. It is the responsibility of the Compliance Committee to maintain contact with outside counsel or other appropriate sources so that the Practice is aware of new regulatory and legal developments affecting its operations. A reasonable amount of hours will be used to appropriately train the employee.

The Compliance Officer, or his or her designee, shall ensure that each new employee or appropriate affiliate receives a copy of the compliance program. The Compliance Officer or his or her designee shall be responsible for training all new employees regarding the requirements of this program and its importance to the Practice.

D. EXIT INTERVIEWS

It shall be the responsibility of the Compliance Officer, or his or her designee, to conduct an exit interview with each employee terminating employment with the Practice. The purpose of this interview shall be to solicit information about the level of the Practice's compliance with the Standards of Conduct. A questionnaire like the one attached at Exhibit 2 shall be completed at each exit interview.

E. DISCIPLINARY ACTIONS

It shall be the responsibility of the Compliance Committee to ensure that any employee or affiliate found to have violated the Standards of Conduct be disciplined in an appropriate, measured, and consistent fashion and in compliance with the Practice's existing discipline policy. In order to make the Practice's compliance program effective, the Compliance Officer, or his or her designee, must educate all employees so that they understand that the program includes the imposition of appropriate discipline for violations of the Standards of Conduct. Violations of the Standards of Conduct (including failure to report the misconduct of other employees or affiliates) may result in punishment, including possible immediate termination of employment.

Certain violations of the compliance program may justify immediate termination. These offenses include:

(1) failure to report conduct by a Practice employee or affiliate that a reasonable person under the circumstances should have known was criminal or a violation of federal or state law;

(2) failure to report a violation of the Standards of Conduct by any Practice employee or affiliate that a reasonable person under the circumstances should have known was a violation of the Standards;

(3) willfully providing materially false information to the Practice, its attorneys, a government agency, or other person in connection with any matter related to the Practice or the provision of any health care service or item; and

(4) taking or attempting to take any retaliatory action against any person for making any compliance report or raising any compliance issue in good faith.

Approved and Adopted This

Signatures of Appropriate Practice Officers:

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EXHIBIT 2

COMPLIANCE PROGRAM EXIT INTERVIEW

This form is an important part of the Practice's Compliance Program. We ask that all employees and others who are terminating their relationship with the Practice take a few moments to respond to the questions that follow. Our goal is to find ways in which we can improve the ethics and compliance of our organization.

1. Name: _____

2. Please provide an address and telephone number where we can reach you after you leave your employment with the Practice:

3. What was your position with the Practice?

4. How long were you employed by the Practice?

5. During your affiliation with the Practice, have you ever been asked to engage in conduct that you believe was either unethical or illegal?

   YES _____ NO _____.

   If yes, by whom? Please describe that conduct, including the relevant dates.

6. During your affiliation with the Practice, have you ever engaged in conduct that you believe was either unethical or illegal?

   YES _____ NO _____.

   If yes, please describe that conduct, including the relevant dates.

7. Have you ever witnessed conduct by an employee, affiliate, contractor or agent of the Practice that you believe was either unethical or illegal?

   YES _____ NO _____.

If yes, by whom? Please describe that conduct, including the relevant dates.

8. During your affiliation with the Practice, has there ever been anything that you have felt uncomfortable doing on behalf of the Practice?

YES _____ NO _____.

If yes, please describe.

9. Have you or any other person ever removed Practice documents without returning them?

YES _____ NO _____.

If yes, what documents and where are they now?

10. Have you ever given Practice documents to a third-party other than in furtherance of the Practice's business?

YES _____ NO _____.

If yes, to whom and when?

11. Do you have any recommendations for improving the Practice's compliance program or its ability to meet its ethical and legal obligations?

YES _____ NO _____.

If yes, what are they?

EXHIBIT 3

VERIFICATION CORRESPONDENCE

_____
_____
_____
_____

Dear _____:

On _____, at approximately _____ am/pm, I spoke to you regarding a question concerning _____
_____
_____
_____

You informed me that _____
_____
_____
_____

If I have misunderstood your guidance in any manner, please write to me as soon as possible. Thank you for your kind attention to this matter.

Sincerely,

_____

cc: Compliance Officer

EXHIBIT 4

COMPLIANCE PROGRAM REPORT FORM

The Compliance Program reporting system was established to help the Practice personnel and affiliates with questions, concerns, and complaints that cannot be properly addressed through traditional resolution processes. It is our intention to respond, as appropriate, to each inquiry which is made in good faith. It is the Practice's policy that no retaliation or retribution occur as a result of using the reporting system. It is also the Practice's policy that the anonymity of individuals using the system be preserved, subject to the limits imposed by law and as otherwise consistent with the Practice's interests. If you discuss your report with other individuals, your anonymity may not be preserved.

In the space provided below, please describe your question, concern or complaint. Feel free to attached additional sheets if necessary. Please be as specific as possible so that we may respond appropriately. Please attach copies of any relevant documents or other materials that you believe would assist in our appropriately investigating your report.

_____

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_____

_____

_____

_____

_____

Name (optional) _____

Address or phone number (optional) _____