GALEN
MEDICAL GROUP

Wisdom. Compassion. Integrity.

PHYSICIAN PRACTICE COMPLIANCE PROGRAM

Amended _5/06/2019___

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GALEN MEDICAL GROUP
COMPLIANCE PROGRAM

INTRODUCTION

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

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

The Compliance Program, having been approved by Galen, constitutes official practice policy, and may be updated periodically. Galen partners, employees and contractors who fail to comply with the elements of this Compliance Program may face disciplinary actions including reprimand, suspension without pay, or termination, as maintaining compliance and reporting non-compliance are essential job functions.

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

Galen is committed to pro-active management of its billing processes in order to ensure full compliance with Medicare and other government regulations and third-party payor requirements. The policies and procedures referenced in this document are meant to transcend all partners, employees, contractors, and vendors of our practice. It is the intention of Galen to enforce all policies and procedures, most importantly those which are designed to detect and prevent issues of non-compliance, so that all reasonable steps necessary to facilitate compliance diligence are enacted. Galen's Compliance Officer should be contacted when questions concerning compliance arise or to report potential violations. At any time, communication to the Compliance Officer,

Savannah Knuettel may occur either by telephone/hotline **(423-308-0280 option 8)**, electronic mail **(compliance@galenmedical.com),** memorandum, or in person. To the extent possible, all communication to the Compliance Officer will be treated confidentially.

A. Benefits of a Compliance Program

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

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

An effective compliance program is essential for physician practices.

All health care providers have a duty to reasonably ensure that the claims submitted are true and accurate. The government continues to engage the provider community in an extensive, good faith effort to work cooperatively on voluntary compliance to minimize errors and to prevent potential penalties for improper billings before they occur. To that end, the government has directed the implementation of compliance programs for the majority of health care providers.

II. COMPLIANCE PROGRAM ELEMENTS

The Seven Basic Compliance Elements

The federal government has set forth seven basic elements necessary for an "effective" compliance program. An effective program to prevent and detect violations of law means a program that has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting improper conduct. Failure to prevent or detect the instant offense, by itself, does not mean that the program was not effective. The hallmark of an effective program to prevent and detect violations of law is that Galen exercised due diligence in seeking to prevent and detect improper conduct by its employees and other agents. In that regard, Galen should take the following types of steps:

1. ***Auditing & Monitoring***

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

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

The practice must establish compliance standards through the development of written policies and procedures.

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

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

4. ***Training***

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

5. ***Response & Correction***

After an offense has been detected, the practice must take all reasonable steps to respond appropriately to the offense and to prevent further similar offenses-including any necessary modifications to its Compliance Program to prevent and detect violations of law.

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

The practice must develop accessible lines of communication to keep practice employees updated regarding compliance activities.

7. ***Enforcement & Discipline***

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

STEP ONE: AUDITING AND MONITORING

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

1. Practice Policies and Procedures

The Compliance Officer will be charged with the responsibility of periodically reviewing the policies and procedures to see if they are current and complete. If the policies and procedures are found to be ineffective or outdated, they will be updated to reflect changes.

2. Claims Submission Audit

In addition to the policies and procedures themselves, bills and medical records will be reviewed for compliance with applicable coding, billing and documentation requirements. The people involved in these self-audits will include the Compliance Officer, person in charge of billing compliance, and a medically trained person (*e.g.*, registered nurse or a physician (physicians can rotate in this position)).

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

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

Audits will examine the claim development and submission process, from patient intake through claim submission and payment, and identify elements within this process that may contribute to non-compliance or that may need to be the focus for improving execution. The audit process will include a consistent methodology for selecting and examining records.

Periodic audits will be conducted at least once each year to ensure that our Compliance Program is being followed. A randomly selected number of medical records will be reviewed to ensure that the billing and coding was performed accurately. If problems are identified, a focused review will be conducted on a more frequent basis. When audit results reveal areas needing additional information or education of employees and physicians, these areas will be incorporated into the training and educational system.

Periodic audits might include the following:

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

One of the most important elements of a successful billing compliance program is appropriate action when a problem is identified in the internal audit. This action should be taken as soon as possible. The specific action that Galen takes will depend on the circumstances of the situation it has identified. In some cases, the action may be as simple as generating a repayment to Medicare or the appropriate payer. In others, Galen may want to seek legal advice and/or consult with a coding/billing expert to determine the next best course of action. There is no boilerplate solution to how to handle problems that are identified.

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

STEP TWO: PRACTICE STANDARDS AND PROCEDURES

1. Code of Conduct

The following statement of practice policy constitutes the Code of Conduct of Galen. It affirms Galen's corporate policy of conducting its business and operations in accordance with both the law and the highest standards of business ethics. Compliance with these provisions is of critical importance. However, these standards will not dispense of the need to become familiar with applicable laws and Galen policies/protocols. If the Compliance Program does not address a particular circumstance or issue, please discuss with the Compliance Officer.

a. The practice requires compliance with all laws and regulations to which Galen is subject and Galen's own policies and procedures . When the application of a law ,regulation, or policy is uncertain, the guidance and advice of Galen's Compliance Officer shall be sought.

b. The practice is dedicated to providing medically necessary health care to patients without regard to color, religion, creed, national origin, (physical, mental or visual) disability, age (forty years or older), veteran or military status, genetic information, sex or gender (including pregnancy, sexual orientation or gender identity), or any other characteristic protected under applicable federal, state or local law. Treatment decisions will be made in accordance with clinical need and with applicable laws and regulations,including a commitment to submit accurate claims consistent with such requirements.

c. It is our policy to maintain contacts with governmental officials and other government personnel, whether directly or indirectly, as proper business relationships. Such contacts must never suggest undue influence upon such persons or cast doubt on Galen's integrity. Furthermore, Galen is committed to ensuring the accuracy of all filings with the government.

d. Galen maintains accurate and reliable corporate records which disclose

disbursements and other transactions to which Galen is a party. All confidential patient and business information shall be safeguarded and shall not be used for personal benefit or gain.

e. Galen requires the undivided loyalty of its employees in the exercise of their practice responsibilities. Except as may be approved otherwise by the Compliance Officer and/or Compliance Committee, personal investments or other activities which may create, or give the appearance of, a conflict of interest are to be avoided.
Here are some other ways in which conflicts of interest could arise:

- Being employed (you or a close family member) by, or acting as a consultant to, a competitor or potential competitor, supplier or contractor, regardless of the nature of the employment, while you are employed with Galen Medical Group
- Hiring or supervising family members or closely related persons.
- Serving as a board member for an outside commercial company or organization.
- Owning or having a substantial interest in a competitor, supplier or contractor.
- Having a personal interest, financial interest or potential gain in any Galen transaction.
- Placing company business with a firm owned or controlled by a Galen employee or his or her family.
- Accepting gifts, discounts, favors or services from a customer/potential customer, competitor or supplier, unless equally available to all Galen employees.

Determining whether a conflict of interest exists is not always easy to do. Employees with a conflict of interest question should seek advice from management. Before engaging in any activity, transaction or relationship that might give rise to a conflict of interest, employees must seek review from their managers or the Compliance department.

f. Galen requires prompt reporting of violations of law, ethical principles, and our policies and procedures to Galen's Compliance Officer or Supervisor. Galen requires full cooperation with audits and investigations. We will not tolerate retaliation against employees who raise genuine ethics concerns in good faith and will respect the confidentiality and anonymity with respects to such disclosures.

g. Galen is dedicated to maintaining a healthy and safe environment. A safety manual has been designed to educate you on safety in the workplace. If you do not know where to locate a copy of this manual, please see your Site Manager.

Galen Medical Group takes seriously the standards set forth in the Code, and violations are cause for disciplinary action up to and including termination of employment.

Do the Right Thing
Several key questions can help identify situations that may be unethical, inappropriate or illegal:

- Does what I am doing comply with Galen's guiding principles, Code of Conduct and company policies?
- Have I been asked to misrepresent information or deviate from normal procedure?
- Would I feel comfortable describing my decision at a staff meeting?
- How would it look if it made the headlines?
- Am I being loyal to my family, my company and myself?
- Is this the right thing to do?

Galen has adopted the foregoing Code of Conduct. All partners, employees, and contractors are expected to adhere to its terms.

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2. Practice Policies and Procedures

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

The Policies and Procedures will be distributed to all partners, employees and contractors and posted on the employee portal. All partners, employees and contractors will be required to certify that they have read, and fully understand, the Policies and Procedures. Certifications for all partners, employees and contractors will be kept on file in Human Resources. Furthermore, adherence to compliance will be an element in evaluating physicians and employees.

3. Specific Risk Areas

Galen is committed to conducting its business in a lawful and ethical manner. Galen's partners, employees, and contractors are required to comply with all applicable laws, regulations, and policies affecting the operations of the practice (some of which are discussed in Appendix C - Statutes). Topics addressed by such laws, regulations, and policies may include the following:

a. Coding and Billing

The identification of risk areas associated with coding and billing is a major part of Galen's Compliance Program. It is important that we accurately make request for reimbursements and that we are accurately reimbursed for the services provided. All partners, employees, and contractors shall be familiar with and follow Galen's billing and collection policies and procedures. Failure to adhere to these policies and procedures, when such results in an overcharge or mis-billing, is not only ethically wrong, but can also lead to criminal and civil liability. Galen is committed to fair and accurate billing and coding that is in accordance with all applicable federal and state laws and third-party payor requirements.

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

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

- upcoding the level of service provided;
- submitting incorrect, misleading, or fraudulent information;
- falsifying, destroying, or illegally withholding records;
- failing to identify and report credit balances;
- signing certifications that are known to be false or misleading;
- failing to adequately and timely notify the applicable payor of a potential overpayment.

b. Reasonable and Necessary Services

Galen's Compliance Program will attempt to ensure that only claims for services that are reasonable and necessary in the particular case are submitted. The government recognizes that physicians should be able to order any tests, including screening tests, they believe are appropriate for the treatment of their patients. However, third-party payors will only pay for services that meet the definition of reasonable and necessary.

Medicare (and many insurance plans) may deny payment for a service that the physician believes is clinically appropriate, but which is not reasonable and necessary. Thus, when a physician provides services to a patient, he or she should only bill those services believed to be reasonable and necessary for the diagnosis and treatment of a patient. Upon request, Galen should be able to provide documentation, such as a patient's medical records and physician's orders, to support the appropriateness of a service that the physician has provided and to support the billing of such procedures in accordance with applicable payor guidelines.

When an item or service may not be covered by a third-party payor, Galen is responsible to convey this information to the patient so that the patient can make an informed decision concerning the health care services he/she may want to receive. Galen conveys this information through, in some cases, Advance Beneficiary Notices (ABNs). 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 the payor does not. The ABN must be sufficient to put the patient on notice of the reasons why the physician believes that the payment may be denied. The objective is to give the patient sufficient information to allow an informed choice as to whether to pay for the service. 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. Accordingly, each ABN should: (1) be in writing; (2) identify the specific service that may be denied; (3) state the specific reason why the physician believes that service may be denied; and (4) be signed by the patient acknowledging that the required information was provided and that the patient assumes responsibility to pay for the service.

Because payors primarily rely on the professional judgment of the treating physician to determine the reasonable and necessary nature of a given service or supply, it is important that physicians provide complete and accurate information on any certifications they sign. Activities such as signing blank certifications, signing a certification without seeing the patient to verify the item or service is reasonable and necessary, and signing a certification for a service that the physician knows is not reasonable and necessary are activities that can lead to criminal, civil and

administrative penalties. Ultimately, it is advised that physicians carefully review any form of certification before signing it to verify that the information contained in the certification is both complete and accurate.

c. Billing for Non-Covered Services as if Covered

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

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

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

d. Billing Practices by Non-Participating Physicians

There are certain limitations regarding what and how a Medicare non-participating physician may charge. If you are a Medicare non-participating provider, please seek guidance from the Compliance Officer regarding what amount can be charged.

e. Professional Courtesy

The term "professional courtesy" is used to describe a number of analytically different practices. The traditional definition is the practice by a physician of waiving all or a part of the fee for services provided to the physician's office staff, other physicians, and/or their families. "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 staff or employees.

In general, whether a professional courtesy arrangement runs afoul of the fraud and abuse laws is

determined by two factors: (i) how the recipients of the professional courtesy are selected; and (ii) how the professional courtesy is extended. If recipients are selected in a manner that directly or indirectly takes into account their ability to affect past or future referrals, the Anti-Kickback Statute -- which prohibits giving anything of value to generate Federal health care program business -- may be implicated. If the professional courtesy is extended through a waiver of copayment obligations (i.e., "insurance only" billing), other statutes may be implicated, including the prohibition of inducements to beneficiaries. Claims submitted as a result of either practice may also implicate the civil False Claims Act.

Thus, the following are general observations about professional courtesy arrangements for consideration:

- A physician's regular and consistent practice of extending professional courtesy by waiving the entire fee for services rendered to a group of persons (including employees, physicians, and/or their family members) may not implicate any of the OIG's fraud and abuse authorities so long as membership in the group receiving the courtesy is determined in a manner that does not take into account directly or indirectly any group member's ability to refer to, or otherwise generate Federal health care program business for, the physician.
- A physician's regular and consistent practice of extending professional courtesy by waiving otherwise applicable copayments for services rendered to a group of persons (including employees, physicians, and/or their family members), would not implicate the Anti-Kickback Statute so long as membership in the group is determined in a manner that does not take into account directly or indirectly any group member's ability to refer to, or otherwise generate Federal health care program business for, the physician. However, any such waiver of copayment practice would implicate section 1128A(a)(5) of the Act if the patient for whom the copayment is waived is a Federal health care program beneficiary who is not financially needy. Thus, waiving any copayments for Federal health care program beneficiaries for any basis other than financial need is prohibited.
- A physician’s regular and consistent practice of extending professional courtesy by waiving other applicable copayments for services rendered to a group of persons (including employees, physicians, and/or their family members), may violate payor contracts which require copayments to discourage overutilization and reduce costs. Thus, waiving any copayments other than financial need is prohibited without the payor’s express approval.

The legality of particular professional courtesy arrangements will turn on the specific facts presented, and, with respect to the Anti-Kickback Statute, on the specific intent of the parties. Consult with the Compliance Officer before extending any professional courtesy arrangements.

f. Documentation

Timely, accurate, legible and complete documentation is critical to nearly every aspect of a physician practice. Therefore, one of the most important physician practice compliance issues is the appropriate documentation of diagnosis and treatment. Physician documentation is necessary

to determine the appropriate medical treatment for the patient and is the basis for coding and billing determinations. Most importantly, failure to document properly has the potential to compromise good patient care. Thorough and accurate documentation helps to ensure accurate recording and timely transmission of information.

1. Medical Record Documentation

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

- The medical record and visits should be completed in a timely manner;
- The documentation of each patient encounter should include the reason for the encounter; any relevant history; physical examination findings; prior relevant diagnostic test results; assessment, clinical impression, or diagnosis; plan of care; and date and electronic signature of the provider;
- Past and present diagnoses should be accessible to the treating and/or consulting physician;
- Appropriate health risk factors should be identified; and
- The patient's progress, his or her response to, and any changes in, treatment, and any revision in diagnosis should be documented.

The CPT and ICD-10-CM codes reported on the health insurance claims form should be supported by documentation in the medical record and should contain all required information. Additionally, third-party payors should be able to determine who provided the services.

2. Claim Form

Another documentation area that Galen will monitor closely is the proper completion of the 1500 claim form. All information included on the claim form should be accurate and complete.

g. Kickbacks, Inducements and Self-Referrals

Galen's Compliance Program will ensure compliance with the federal Anti-Kickback Statute, and the Physician Self-Referral Law (*i.e.*, "Stark Law"). Remuneration for referrals is illegal because it can distort medical decision-making, cause overutilization of services or supplies, increase costs to Federal health care programs, and result in unfair competition by shutting out competitors who are unwilling to pay it. Remuneration for referrals can also affect the quality of patient care by encouraging physicians to order services or supplies based on profit rather than the patients' best medical interests. In particular, arrangements with hospitals, hospices, nursing facilities, home health agencies, durable medical equipment suppliers and vendors are areas of potential concern.

In general, the Anti-Kickback Statute prohibits knowing and willfully giving or receiving anything of value to induce referrals of Federal health care program business. It is generally recommended that all business arrangements wherein physician practices refer business to an outside entity or receive referrals from an outside entity should be on a *fair market value* basis. Whenever a physician practice intends to enter into a business arrangement that involves its making and receiving referrals, the arrangement should be reviewed by the Compliance Officer and/or counsel familiar with the Anti-Kickback Statute and the Stark Law.

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

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

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

In order to keep current with this area of the law, Galen will stay up to date, on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, of all relevant OIG Special Fraud Alerts and Advisory Opinions to ensure that practice policies reflect current positions and opinions. Please see Appendix C containing a detailed description of the Federal Anti-Kickback Statute, Stark Law, and other applicable laws.

h. Vendor Relationships.

A. The selection of and conduct of business with a Vendor should be solely on the basis of arm's length (i.e., free from improper or inappropriate influence) and appropriate business, medical, clinical, and/or research criteria, as applicable, such as cost effectiveness and quality.
B. Employees should conduct business with Vendors in a way that maximizes the ability of Galen to carry out its patient care and in accordance with legal and ethical standards aimed at preventing conduct that may inappropriately influence purchasing decisions or be perceived as doing so.
C. Galen employees and Providers are held to high standards with respect to appropriate dealings with third parties. Many practices that are common in other industries are illegal

or prohibited in the case of a health care organization, physicians, other health care providers, and companies engaged in the manufacture, distribution, marketing or sale of pharmaceuticals, medical devices, and other clinical equipment, products and supplies. Federal and state laws set strict standards for relationships between providers and Vendors. In all interactions with or on behalf of Vendors, Galen will endeavor to adhere to all relevant legal standards and the highest standards of ethics and integrity.

i. Consulting, Speakers' Bureaus and Other Business Arrangements.

Providers may serve as paid consultants or advisors to vendor corporations in accordance with Galen policies and other applicable laws.

A. Providers may receive complimentary meals and travel arrangements from a vendor only in direct relation to their work for the vendor as a paid consultant or advisor.
B. Consulting or advisory relationships should be entered into by Galen Providers carefully. The work that will be done for the vendor corporation must be:
    a. Generally commensurate with the amount of compensation provided by the vendor and
    b. The compensation must approximate fair market value as determined by acceptable benchmarks (e.g. MGMA practicing physician salary benchmarks)
    c. A signed agreement that outlines, at a minimum, the work to be done for the vendor corporation and the compensation to be provided by the vendor.
    d. If there are any concerns that a consulting arrangement could be considered "token consulting" please bring this to the attention of the Compliance Committee, Medical Director, or the President.

j. Conflict of Interest.

Unless otherwise prohibited by contract, Galen recognizes and respects the rights of its partners, employees, and contractors to engage in outside financial, business or other activities as long as those activities are legal and do not impair or interfere with the performance of Galen's duties. Outside activities must not involve the misuse of Galen's name, reputation, influence, facilities or other resources. Partners, employees, and contractors are prohibited from using their positions to influence Galen's business, administrative, or other decisions in a way that could lead to personal financial gain or advantage for that individual or his/her family or business. Galen expects that all partners, employees, and contractors will put the interests of Galen ahead of their other business concerns, and will not seek to benefit themselves at the expense of Galen.

Similarly, partners, employees, and contractors are prohibited from assuming obligations outside Galen or elsewhere which interfere with them adequately discharging their obligations and commitments to Galen. Generally, it is almost always a conflict of interest for an employee to work simultaneously for Galen and a competitor or supplier, and partners, employees, and contractors should not engage in activities which create a conflict of interest. When potential conflicts arise, disclosure and resolution of conflicts of interest must be made in writing to the Compliance Officer. The failure to disclose a conflict of interest or the failure to eliminate a conflict when so directed may be grounds for disciplinary action up to, and including, discharge.

Please see H.R. 4.5 Conflicts of Interest Policy.

k. Gifts and Gratuities

Closely linked to concerns about actual or perceived conflicts of interest is the issue of giving or receiving gifts, meals and entertainment. As a general rule, partners, employees, and contractors who participate in purchasing, ordering, or referring decisions are prohibited from accepting personal gifts, services, gratuities, or other things of value for themselves or for members of their immediate families from organizations with which Galen does business or refers to. In addition, such persons are prohibited from giving personal gifts, services, gratuities, or other things of value in exchange for referrals to Galen. However, we recognize that giving and receiving gifts, meals, refreshments, and entertainment in the course of carrying out business is a customary practice and may be appropriate and legally compliant under certain circumstances. Accordingly, receiving or giving amenities such as modest meals, educational gifts, and refreshments of a nominal value (no more than $10 individually; no more than $50 in the aggregate annually per person) are acceptable as long as they are associated with a business and/or educational purpose, are appropriate as to time and place, do not influence or give the appearance of influencing the recipient, and have been approved by the Compliance Officer. While there is no checklist for determining what is inappropriate, the following gifts are strictly prohibited: payments of or receipt of cash or cash equivalents (*e.g.*, gift cards); providing or accepting lavish and/or personal gifts, such as tickets to sporting events, jewelry, boats and cars; and; providing or accepting trips, vacations or expensive meals.

If there is any possibility whatsoever that giving or receiving a gift could be viewed or later construed as a bribe or improper inducement, you must not give or accept the gift. In addition, any gifts which you give should not violate the standards of conduct of the recipient's organization or applicable legal requirements.

l. Marketing Practices

Galen may use marketing and advertising activities to educate the public, increase awareness of our services, and to recruit personnel. In doing so, we will only present truthful, fully informative, and non-deceptive information which is consistent with the laws and regulations that govern our marketing and advertising activities.

m. Protecting Galen Assets

Galen has many valued assets, including its physical property, proprietary trade secrets and confidential information. Protecting these assets against loss, theft and misuse is everyone's responsibility. Our property may not be used for personal benefit, nor may it be sold, loaned, given away or disposed of, without proper authorization. Galen's assets must only be used for our business purposes. Anyone aware of any loss or misuse of assets should report it to our Compliance Officer.

Our assets are not limited to physical property. Partners, employees, and contactors may have access to intangible assets belonging to Galen, which consist of intellectual property, such as

trademarks and copyrights, and proprietary information and trade secrets, such as confidential data, computer programs, designs, logos, service marks, and business expertise. These intangible assets must be protected. Unauthorized disclosure of this information could destroy its value to Galen and give an unfair advantage to our competitors.

To ensure confidentiality of our information, partners, employees, and contractors must not disclose our trade secrets or other confidential information, either during or after employment or the contract period, except to people authorized by Galen and bound by confidentiality to the practice. Similar restrictions, usually spelled out in our contracts, apply to information obtained from our vendors and suppliers. Galen's vendors and suppliers have placed their trust in us not to reveal their confidential information, and we must comply with these restrictions.

n. Drugs and Devices

The distribution or use of unapproved drugs or devices and the use or distribution of adulterated or misbranded drugs or devices is expressly prohibited. Only drugs, devices and procedures which have been approved by the government (*e.g.,* the FDA) may be used or dispensed. Violation of federal and state laws regulating drugs and devices (including FDA requirements) can lead to fines and imprisonment.

Distribution of an unapproved, adulterated or misbranded drug or device can take many different forms:

- Representing a drug or device as something that it is not.
- Selling, distributing or prescribing a counterfeit drug.
- Altering, obliterating, or removing all or part of the label of a drug or device.
- Use or prescription of a drug or device which you are not licensed to use or prescribe.

There are also a number of laws that relate to the specific use of drug samples. No partner, employee, or contractor shall sell, purchase, or trade any drug sample. Only physicians or physician extenders licensed to prescribe the drug, or health care professionals acting at the direction and under the supervision of such a physician or extender, can distribute samples to patients.

When dealing with narcotic drugs, any prescription must be for an approved drug and must be prescribed for a legitimate medical purpose in the usual course of professional practice.

o. Fair Dealing

All partners, employees, and contractors should endeavor to deal fairly and honestly with Galen patients, suppliers, vendors, competitors, officers, referring providers, and employees in a manner compliant with applicable law. You should not take unfair advantage of anyone through manipulation, concealment, abuse of privileged information, misrepresentation of material facts,

or any other unfair dealing practice. In no event shall anyone use any trade secrets, proprietary information or other similar property, acquired in the course of his or her employment with another employer, in the performance of his or her duties for or on behalf of Galen. No one should make disparaging, false or misleading remarks about other companies, including Galen's competitors.

4. Retention of Records

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

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

Medical records will be retained, maintained, and secured in accordance with state and federal requirements. Medical records shall be held in the strictest confidence. For additional information regarding the security of medical records, please see Galen's HIPAA Compliance Policies.

STEP THREE: DESIGNATION OF A COMPLIANCE OFFICER/CONTACT

Galen has appointed a Compliance Officer. The Compliance Officer is responsible for overseeing implementation of this Compliance Program, making recommendations to practice management regarding changes to the practice to enhance compliance, updating the Compliance Program and serving as liaison to the employees and physicians of Galen.

The Compliance Officer will be assisted by a Compliance Committee who shall assist with the compliance efforts of Galen, as need be. The Compliance Committee shall consist of the following individuals: President, Medical Director, Compliance Officer, Administrator, Director of Revenue Cycle , Director of Operations, Physician leadership appointed by the President, and

as needed HIPAA Security Officer, Health Information Director, and Finance Director

The Compliance Officer has the following specific responsibilities:

- Overseeing and monitoring the implementation of the Compliance Program;
- Reporting on a regular basis to the governing body, CEO, and Compliance Committee;
- Establishing methods, such as periodic audits, to improve the practice's efficiency and quality of services, and to reduce the practice's vulnerability to fraud and abuse;
- Ensuring that partners, employees, and contractors are aware of Galen's Compliance Program requirements;
- Periodically revising the Compliance Program in light of changes in the needs of the practice or changes in the law and in the policies and procedures of Government and private payer health plans;
- Developing, coordinating and participating in a training program that focuses on the elements of the Compliance Program, and seeks to ensure that training materials are appropriate;
- Ensuring that the HHS-OIG's List of Excluded Individuals and Entities, and the General Services Administration's List of Parties Debarred from Federal Programs have been checked with respect to all employees, medical staff and applicable contractors;
- Ensuring that partners, employees and contractors know, and comply with, pertinent Federal and State statutes, regulations and standards; and
- Investigating any report or allegation concerning possible unethical or improper business practices, and monitoring subsequent corrective action and/or compliance.

Use of Outside Counsel: The Compliance Officer, Compliance Committee, and the governing body members shall have the authority to contact outside counsel for advice and assistance with any issues involved in the implementation, development and auditing/investigating of this Compliance Program.

STEP FOUR: CONDUCTING EFFECTIVE TRAINING AND EDUCATION

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

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

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

Training will be accomplished through a variety of means, including in-person training sessions (*i.e.*, either on site or at outside seminars), through online training, handouts, information posted on the employee portal. Regardless of the training modality used, Galen will ensure that the necessary education is communicated effectively. Simply providing individuals with documents for their own reading and comprehension will not be considered sufficient.

1. Compliance Training

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

All employees will receive training on (1) how to perform their jobs in compliance with the standards of the practice and any applicable regulations, and (2) procedures for reporting compliance violations and the disciplinary system. Each employee should understand that compliance is a condition of continued employment. Compliance training will center on explaining why the practice is developing and establishing written policies and procedures. The training will emphasize that following the policies will not get a practice employee in trouble, but violating the policies will. To the extent feasible, new employees will be trained on the Compliance Program within 60 days of their start date and such training will be documented. Thereafter, employees should receive refresher training on an annual basis or as appropriate, and such training will be documented. Attendance and participation in training and education programs is a condition of continued employment and retention, and the failure to comply can result in disciplinary action.

2. Coding and Billing Training

Coding and billing training on the Federal health care program requirements may be necessary for certain members of the staff depending on their respective responsibilities. Individuals who are directly involved with billing, coding or other aspects of the Federal health care programs will receive education specific to that individual's responsibilities. Items that may be discussed relative to coding and billing training might include:

- coding requirements;
- claim development and submission processes;
- marketing practices that reflect current legal and program standards;
- the ramifications of submitting a claim for physician services when rendered by a non-physician;
- signing a form for a physician without the physician's authorization;
- the ramifications of altering medical records;
- proper documentation of services rendered;
- how to report misconduct;
- proper billing standards and procedures and submission of accurate bills for services or items rendered;

- the personal obligation of each person involved in the billing process to ensure claims are properly and accurately submitted; and
- the legal sanctions for submitting deliberately false or reckless billings.

Galen will also work with its third-party billing company, if one is used, to ensure that documentation is of a level that is adequate for the billing company to submit accurate claims on behalf of the physician practice.

3. Format of the Training Program

Training may be conducted either in-house or by an outside source. Training at outside seminars, instead of internal programs and in-service sessions, can be an effective way to achieve Galen's training goals. For recordkeeping purposes, the Compliance Officer shall be notified of attendance and participation in training and education activities not offered through Galen.

As part of the training, Galen will make sure all employees are familiar with at least pertinent risk areas. In addition to the training, Galen will be certain that updated ICD-10, HCPCS and CPT manuals (in addition to the carrier bulletins construing those sources) are available to all employees involved in the billing process. A source of continuous updates on current billing policies will also be available.

All in-service training and continuing education should integrate compliance issues, as well as other core values adopted by Galen, such as quality improvement and improved patient service.

4. Continuing Education on Compliance Issues

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

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

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

There are several key warning signs of when the Compliance Program is not working well, *e.g.*, high rates of rejected and/or suspended claims and the placement of a practice on pre-payment

review by the carrier. These warning signs will be followed up on immediately and the compliance procedures will be changed to prevent the problem from recurring.

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

After an offense has been detected, Galen will take all reasonable steps to respond to the offense and to prevent similar offenses. The Compliance Officer will work together with the appropriate department heads to conduct a full internal investigation of all reports of detected violations. The goodwill generated by the development of our Compliance Program will quickly dissipate if the practice ignores reports of possible fraudulent activity.

The Compliance Officer may consult with or instruct legal counsel to conduct the investigation. A complete and accurate record of each investigation, including recommendations for corrective action, shall be prepared by the Compliance Officer at the request of legal counsel. Upon the conclusion of an investigation, the Compliance Officer will recommend corrective action.

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

STEP SIX: DEVELOPING EFFECTIVE LINES OF COMMUNICATION

An open line of communication is essential to proper implementation of our Compliance Program. The OIG has encouraged the use of several forms (*e.g.*, hotlines and e-mail) of communication between the Compliance Officer/Compliance Committee and provider personnel.

Galen's Compliance Program system for effective communication will include the following (As discussed in further detail herein):

- the requirement that employees report conduct that a reasonable person would, in good faith, believe to be fraudulent or erroneous;
- creation of a user-friendly hotline and e-mail address, for effectively reporting fraudulent or erroneous conduct;
- provisions in the policies and procedures that state that a failure to report fraudulent or erroneous conduct is a violation of the Compliance Program;
- development of a simple and readily accessible procedure to process reports of fraudulent or erroneous conduct;

- utilization of a process that maintains the confidentiality of the persons involved in the alleged fraudulent or erroneous conduct and the person making the allegation; and
- provisions in the policies and procedures that there will be no retribution for reporting conduct that a reasonable person acting in good faith would have believed to be fraudulent or erroneous.

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

1. Hotline and Other Mechanisms for Reporting Violations

All Galen physicians, employees and contractors are required to report incidents of violations of this Compliance Program, unethical conduct, or incidents or potential fraud and abuse to the Compliance Officer. Such reports may be made in person, through Galen's privacy hotline **(423-308-0280 option 8)**, e-mail **(privacy@galenmedical.com)** or other forms of written communication. Reports will be treated as confidential to the extent reasonably possible.

2. Protection of Employees

It is the policy of Galen that no employee shall be punished solely on the basis that he or she reported what he or she reasonably believed in good faith to be an act of wrongdoing or a violation of this Compliance Program or the practice's Code of Conduct. Furthermore, Galen is committed to following the protections set forth by federal law.

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

STEP SEVEN: ENFORCING STANDARDS THROUGH WELL-PUBLICIZED DISCIPLINARY GUIDELINES

Galen's enforcement and disciplinary policies will ensure that violations of the practice's compliance policies will result in consistent and appropriate sanctions, including the possibility of termination, against the offending individual. At the same time, Galen's enforcement and disciplinary procedures will be flexible enough to account for mitigating or aggravating

circumstances. Individuals who fail to detect or report violations of the Compliance Program may also be subject to discipline. Disciplinary actions may include: warnings (oral); reprimands (written); probation; demotion; temporary suspension; discharge of employment; restitution of damages; and referral for criminal prosecution.

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

III. DEPARTING EMPLOYEES - EXIT INTERVIEW

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

IV. GOVERNMENT INVESTIGATIONS

If any physician or employee of the practice is contacted (e.g., inquiry, subpoena, personal visit) by a governmental agency regarding Galen business, Galen partners, employees and subcontractors are required to notify the Compliance Officer immediately. Retain a copy of any documentation provided to you. While it is practice policy to cooperate with governmental agencies, Galen's legal rights must be protected. In the case where a governmental agent visits an employee, partner or subcontractor, the agent should be asked to contact the Compliance Officer to arrange an interview. The Compliance Officer, in turn, will notify legal counsel to discuss the matter. Do not provide any documentation without being authorized to do so by the Compliance Officer. (See Appendix B for information on the rights and obligations of interviewed individuals.)

V. REPORTING INTENTIONAL WRONGDOING TO AUTHORITIES

It shall be Galen's policy to carefully evaluate all allegations of wrongdoing to determine: (1) if the allegation appears to be well-founded and (2) whether the allegation warrants reporting to enforcement authorities. When billing errors have been reported and payments returned,

unless there is evidence of a pattern or an attempt to conceal intentional wrongdoing, no further reporting to enforcement authorities is required.

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

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

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

VI. COMPLIANCE PROGRAM MODIFICATIONS

It shall be the duty of the Compliance Officer to monitor, on a regular basis, developments in all applicable laws which might affect Galen. If necessary, the Compliance Officer will make appropriate modifications and potential design changes to ensure the continued effectiveness of the Compliance Program.

VII. CONCLUSION

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

It is not feasible to describe every type of business practice that may raise concerns under the areas discussed herein. Accordingly, in the event anyone has any questions about a particular situation or how guidance is interpreted or applied, please contact the Compliance Officer.

APPENDIX A: EXIT INTERVIEW QUESTIONNAIRE

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

1. Have you ever engaged in conduct as a Galen employee which you believe was either unethical or illegal?

2. Have you ever been asked to engage in conduct you believe was either unethical or illegal? If so, by whom?

3. Have you ever witnessed conduct by any Galen employee you believe was unethical or illegal? If so, by whom?

4. Have you heard substantive rumors or reports (*i.e.*, those you felt had some believability) of unethical or illegal conduct by other Galen employees? If so, by whom?

5. Have you ever removed Galen documents (including documents created by you) without returning them to Galen?

6. Do you now have copies of any Galen documents anywhere off premises? Have you ever given Galen documents to any non-Galen employee?

7. Do you know of any Galen employee who has handled company documents in the manner described in questions #5 and #6?

8. Has any government investigator, agent or attorney interviewed you or asked to interview you about possible unethical or illegal conduct related to Galen?

9. While an employee of Galen, did you or any family member own, operate, invest in, assist or otherwise have an interest in Galen or any enterprise which competes with Galen?

_____ Interview Date: _____
Employee Signature

_____
Interview Conducted By:

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

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

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

APPENDIX C: STATUTES

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

Analysis of practices under the fraud and abuse statutes is complex and depends on the specific facts and circumstances. Partners, employees, and contractors shall not make unilateral judgements regarding the permissibility of a particular billing, payment, investment, or discount activity or other suspect arrangements. Such issues must be brought to the attention of the Compliance Officer for review. If anyone has any questions regarding fraud and abuse or applicable laws, consult with the Compliance Officer prior to taking action or engaging in activities which may put Galen at risk.

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

Description of Unlawful Conduct

False Statements and Representations

It is a crime to knowingly and willfully:

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

Anti-Kickback Statute

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

- for the referral of an individual to another for the purpose of supplying items or services that are covered by a Federal health care program; or
- for purchasing, leasing, ordering, or arranging for any good, facility, service, or item that is covered by a Federal health care program.

There are a number of limited exceptions to the law, also known as "safe harbors," which provide immunity from criminal prosecution and which are described in greater detail in the statute and related regulations (found

at 42 CFR § 1001.952). All elements of the applicable safe harbor must be met in order for the immunity to apply. Current safe harbors include:

- investment interests;
- space rental;
- equipment rental;
- personal services and management contracts;
- sale of practice;
- referral services;
- warranties;
- discounts;
- employment relationships;
- waiver of beneficiary co-insurance and deductible amounts;
- group purchasing organizations;
- practitioner recruitment;
- investments in group practices;
- referral arrangements for specialty services;
- ambulatory surgical centers;
- price reductions offered to eligible managed care organizations;
- electronic health record items and services;
- increased coverage or reduced cost sharing under a risk-basis or prepaid plan;
- charge reduction agreements with health plans;
- federally qualified health centers and Medicare Advantage Organizations;
- Medicare coverage gap discount program;
- local transportation;
- OB malpractice insurance subsidies; and
- ambulance restocking.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment, or both. In addition, the provider can be excluded from participation in Federal health care programs.

Examples

- Dr. X accepted payments to sign Certificates of Medical Necessity for durable medical equipment for patients she never examined.

- Home Health Agency disguises referral fees as salaries by paying referring physician Dr. X for services Dr. X never rendered or by paying Dr. X. a sum in excess of fair market value for the services he rendered.
- Dr. X provided free office space one day a week to Dr. Y who refers Medicare beneficiaries to Dr. X.

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

Description of Unlawful Conduct

Physicians (and immediate family members) who have an ownership, investment or compensation relationship with an entity providing "designated health services" are prohibited from referring patients to such entity for these services where payment may be made by a Federal health care program unless a statutory or regulatory exception applies. The Stark Law is a strict liability statute, meaning specific intent is not required. If a prohibited arrangement exists and no exception is satisfied, there is a Stark Law violation. An entity providing a designated health service is prohibited from billing for the provision of a service that was provided based on a prohibited referral. Designated health services include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment and supplies; prosthetics, orthotics, prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

Exceptions for Ownership or Compensation Arrangements

1. physician's services;
2. in-office ancillary services;
3. services furnished by an organization to enrollees;
4. academic medical centers;
5. implants furnished by an ASC;
6. EPO and other dialysis-related drugs;
7. Preventive screening tests, immunizations, and vaccines;
8. Eyeglasses and contact lenses following cataract surgery; and
9. Intra-family rural referrals.

Exceptions for Ownership or Investment Interests

1. ownership of investment securities which may be purchased on terms generally available to the public on the open market;
2. ownership of shares in a regulated investment company as defined by Federal law, if such company had, at the end of the company's most recent fiscal year, or on average, during the previous three fiscal years, total assets exceeding $75,000,000;
3. hospital in Puerto Rico;
4. rural provider; and
5. hospital ownership (whole hospital exception).

Exceptions Relating to Other Compensation Arrangements

1. rental of office space and rental of equipment;
2. bona fide employment relationship;

3. personal service arrangement;
4. physician recruitment;
5. isolated transactions;
6. certain group practice arrangements with a hospital;
7. payments by a physician for items and services;
8. charitable donations by a physician;
9. non-monetary compensation up to a threshold;
10. fair market value compensation;
11. medical staff incidental benefits;
12. risk-sharing arrangement;
13. compliance training;
14. indirect compensation arrangements;
15. referral services;
16. OB malpractice insurance subsidies;
17. professional courtesy;
18. retention payments in underserved areas;
19. community-wide health information systems;
20. e-prescribing;
21. EHR;
22. assistance to compensate a non-physician practitioner; and
23. timeshare arrangements.

Penalty for Unlawful Conduct

Violations of the statute subject the billing entity to denial of payment for the designated health services, refund of amounts collected from improperly submitted claims, and monetary penalties. In addition, the physician can be excluded from participation in Federal health care programs.

Examples

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

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

Description of Unlawful Conduct

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

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

Additionally, the CMPL contains various other prohibitions, including:

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

The term "should know" means that a provider: 1) acted in deliberate ignorance of the truth or falsity of the information; or 2) acted in reckless disregard of the truth or falsity of the information.

Penalty for Unlawful Conduct

Violation of the CMPL may result in a penalty, imprisonment, or both. In addition, the provider may be excluded from participation in Federal health care programs.

Examples

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

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

Description of Unlawful Conduct

This is the law most often used to bring a case against a health care provider for the submission of false claims to a Federal health care program (or an agency thereof). The False Claims Act prohibits knowingly presenting (or causing to be presented) to the Federal Government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the Federal Government or it agents, like a carrier, other claims processor, or state Medicaid program. Claims rendered in violation of the Anti-Kickback Statute or the Stark Law may also trigger liability under the False Claims Act.

Definitions

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

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

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

Deliberate Ignorance - To act in "deliberate ignorance" means that the provider has deliberately chosen to ignore the truth or falsity of the information on a claim submitted for payment, even though the provider knows, or has notice, that information may be false.

Reckless Disregard - To act in "reckless disregard" means that the provider pays no regard to whether the information on a claim submitted for payment is true or false.

Penalty for Unlawful Conduct

A violation of the False Claims Act is a felony, punishment by imprisonment and significant fines. Civil damage suits are also possible, which can lead to awards of monetary damages.

Examples

- A physician submitted claims to Medicare and Medicaid representing that he had personally performed certain services when, in reality, the services were performed by a non-physician and they were not reimbursable under the Federal health care programs.

- Dr. X intentionally upcoded office visits and angioplasty consultations that were submitted for payment to Medicare.
- Dr. X, a podiatrist, knowingly submitted claims to the Medicare and Medicaid programs for non-routine surgical procedures when he actually performed routine, non-covered services.
- Dr. X discovered a Medicare overpayment and failed to return the overpayment to Medicare within sixty (60) days.

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

Mandatory Exclusion

Individuals or entities convicted of the following conduct must be excluded from participation in Medicare and Medicaid:

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

Permissive Exclusion

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

- a criminal offense related to the delivery of an item or service under Medicare or Medicaid;
- a misdemeanor related to fraud, theft, embezzlement, breach of fiduciary responsibility or other financial misconduct against a health care program financed by any Federal, State, or local government agency;
- interference with, or obstruction of, any investigation into certain criminal offenses;
- a misdemeanor related to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance;
- license revocation or suspension;
- exclusion or suspension under a Federal or State health care program;
- submission of claims for excessive charges, unnecessary services or services that were of a quality that fails to meet professionally recognized standards of health care;
- violating the civil monetary penalties law or the statute entitled "Criminal Penalties for Acts Involving Federal Health Care Programs";
- ownership or control of an entity by a sanctioned individual or immediate family member (spouse, natural or adoptive parent, child, sibling, stepparent, stepchild, stepbrother or stepsister, in-laws, grandparent and grandchild);

- failure to disclose information required by law;
- failure to supply claims payment information; and
- defaulting on health education loan or scholarship obligations.

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

If a provider is excluded, the provider (or his/her employer) may not bill a Federal health care program for services provided.

Examples

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

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

Description of Unlawful Conduct

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

Penalty for Unlawful Conduct

The penalty may include the imposition of fines, imprisonment, or both.

Examples

- Dr. X, a chiropractor, intentionally billed Medicare for physical therapy and chiropractic treatments that he never actually rendered for the purposes of fraudulently obtaining Medicare payments.
- Dr. X, a psychiatrist, billed Medicare, Medicaid, TRICARE, and private insurers for psychiatric services that were provided by his nurses rather than himself.

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

Description of Unlawful Conduct

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

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment, or both.

Example

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

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

Description of Unlawful Conduct

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

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment, or both.

Example

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

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

Description of Unlawful Conduct

It is a crime to willfully prevent, obstruct, mislead, delay or attempt to prevent, obstruct, mislead, or delay the communication of records relating to a Federal health care offense to a criminal investigator.

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment, or both.

Examples

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

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

Description of Unlawful Conduct

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

Penalty for Unlawful Conduct

The penalty may include the imposition of a fine, imprisonment, or both.

Examples

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

XI. Unlawful Advertising (42 U.S.C. 1320b-1c)

Description of Unlawful Conduct

42 U.S.C. 1320b-10 makes it unlawful for any person to advertise using the names, abbreviations, symbols, or emblems of the Social Security Administration, Health Care Financing Administration, Department of Health and Human Services, Medicare, Medicaid or any combination or variation of such words, abbreviations, symbols or emblems in a manner that such person knows or should know would convey the false impression that the advertised item is endorsed by the named entities.

Penalty for Unlawful Conduct

A violation of this section may result in a monetary penalty.

Example

- For instance, a physician may not place an ad in the newspaper that reads "Dr. X is a cardiologist approved by both the Medicare and Medicaid programs."

XII. Anti-Trust

The principal purpose of the antitrust laws is to maintain a free enterprise system by prohibiting business activities that unreasonably restrain trade or lessen competition. While there is a complex body of antitrust law, there are certain basic principles that should guide business activities:

- Do not discuss price with competitors. Any agreement or understanding by which two or more competitors agree to raise, lower, or stabilize prices is considered illegal and price-fixing (*e.g.*, agreements among competing health care providers concerning the price to be charged to patients or third-party payers for their services; discussions about or disclosure of factors that relate to price, such as costs and per diem charges).
- Do not discuss market division or allocation with competitors. Allocation or division of markets on any basis (geographic, product, or service) is illegal (*e.g.*, agreements among competing health care providers as to which provider will provide certain types of services or which provider will provide services in a particular geographic area).
- Do not engage in group boycotts. While any person or entity, acting in its own self-interest, can refuse to deal with anyone it chooses, an agreement among competitors to refuse to deal is illegal (*e.g.*, an agreement among competing heath care providers not to deal with a managed care organization).

The greatest antitrust risk comes from interactions with our competitors. All partners, employees, and contractors should refrain from discussing Galen's costs and pricing information, expansion and development plans, anticipated acquisitions or divestitures, or similar matters with competitors. Such discussions could be used improperly, or could support the contention that we may have conspired to agree upon pricing, customer allocations, markets or the like. All partners, employees, and contractors should also actively avoid any attempts by competitors to discuss these topics, and if unable to do so, should leave any meeting where such discussions are taking place, and report the issue immediately to the Compliance Officer.

XIII. Additional Information

Additional information regarding criminal and civil statutes concerning health care fraud and abuse is available from the U.S. Department of Health and Human Services Office of Inspector General at www.oig.hhs.gov.