I. INTRODUCTION

In response to growing public concern about fraud and abuse in the health care industry, Congress has armed health care law enforcement officials with an impressive arsenal of state and federal laws aimed at finding, punishing, and deterring fraud and abuse—with physicians as a main target. States are following the federal model by creating local laws and regulations that mimic, and often expand upon, the federal regulatory scheme. The federal and state laws are complex and the potential penalties severe. Physicians who fail to make efforts to understand and follow the rules may unwittingly stumble into very serious trouble.

Having already issued guidance documents for hospitals, nursing homes, billing companies, and many other sectors of the health care industry, the Office of the Inspector General (“OIG”) of the Department of Health and Human Services in October 2000 issued a guidance document setting forth suggestions and recommendations for elements of an effective compliance program for individual and small group physician practices. This guidance is intended to help physicians avoid billing and coding violations and the investigations and prosecutions associated with such transgressions. (The OIG’s compliance guidance documents are available on the OIG website at http://oig.hhs.gov/modcomp/index.htm.)

In recent years, numerous medical practices have been subject to significant penalties for unwitting violations of the Medicare or Medicaid reimbursement rules. An effective compliance plan can save an organization from the devastating expenditure of time, money, and aggravation that such investigations inflict, not to mention the inestimable damage to professional reputation. Given the complexity and risks associated with participation in the Medicare and Medicaid programs, compliance plans have become a practical necessity for many individual physicians, group practices, and other medical providers (collectively referred to as “medical practices”). This document will help readers decide what kind of compliance plan is right for a given medical practice, or to assess whether an existing plan effectively protects the practice.

II. THE WAR ON HEALTH CARE FRAUD

These days, the government frequently makes headlines by announcing another charge, conviction, or settlement of a health care fraud case. National antifraud initiatives have been tagged with catchy names like the Physicians at Teaching Hospitals (“PATH”) audits, “Operation Restore Trust,” and “Operation Bad Bundle,” each of which examines, among other things, the billing and coding activities of various health care providers. The Department of Justice (“DOJ”) has identified health care fraud as one of its top enforcement priorities.

In addition to these national investigations against institutional health care providers, the government has stepped up enforcement actions against medical practices. In fact, the federal government and the American Association of Retired
Persons have gone so far as to announce a program called “Who Pays? You Pay” to train Medicare beneficiaries to spot and report aberrations in their physicians’ billing. Patients who turn in their doctors may be eligible for a bounty of up to $1,000 if their reports uncover fraudulent practices. Various states are joining the federal government in the fraud fight, and many similar, smaller scale state initiatives are underway.

Congress has contributed to the enforcement mania over health care fraud and abuse by enacting the Health Insurance Portability and Accountability Act of 1996, and the Balanced Budget Act of 1997, which created new weapons and funding for fighting health care billing fraud. These laws are particularly powerful because they allow for treble damages (i.e., triple the amount of overpayment) and up to $10,000 per false claim filed. As a result, a few thousand dollars in overpayments can lead to millions of dollars in potential liability. The OIG and DOJ have wielded the threat of huge False Claims Act fines and exclusion from Medicare or Medicaid as a club to force health care providers, including medical practices, to accept lower, but still onerous, settlements.

The False Claims Act also allows private parties to bring actions on behalf of the government and keep up to 25% of the total recovery. This means that a patient or an employee of a medical practice could bring a whistleblower action against the practice.

Improper referral arrangements under Stark II or the Anti-Kickback law can lead to substantial civil penalties (up to $15,000 per claim under Stark II and up to $50,000 for an anti-kickback violation) and exclusion from Medicare or Medicaid for up to five years. The same conduct may be actionable under more than one law, stacking the penalties on top of one another. Moreover, illegal kickbacks and other fraudulent conduct can be punished by criminal fines and imprisonment.

III. WHY DEVELOP A VOLUNTARY COMPLIANCE PROGRAM?

Physician practices are not required to have a compliance program. However, there are several reasons for individual physicians and group practices to consider doing so. The OIG has stated that the adoption of a voluntary compliance program will benefit the individual and small group physician practices in the following ways:

- Speed and optimize claim payments;
- Minimize billing mistakes;
- Reduce chances of CMS or OIG audits;
Avoid violations of “Stark II” physician self-referral and anti-kickback laws; and

Mitigate the results of CMS, OIG or DOJ investigations by demonstrating that the physician or physician practice has made a good faith effort to ensure that all claims are submitted properly.

IV. SPECIAL STANDARDS FOR PHYSICIAN COMPLIANCE PLANS

In its guidance for individual and small group practices, the OIG acknowledges that physician practices, particularly smaller physician practices, do not have the economic resources of a hospital or third-party company to institute a large-scale compliance program. Therefore, the physician guidance document stresses the following special considerations for small medical practices:

- Failure to have a compliance program will not be an aggravating factor if a medical practice is subject to federal audit or investigation.
- The OIG will take a much more flexible approach in assessing physician compliance efforts, including the effectiveness of the practice’s compliance plan, if any. For instance, the OIG permits medical practices to outsource their compliance efforts, share compliance officers, or share training programs with other entities.
- The OIG will not take steps to punish innocent or inadvertent errors. There must be evidence of repeated, deliberate, or reckless violations or fraud to justify a referral to DOJ for prosecutions.
- The OIG does not expect small medical practices to comply with every recommended element of an effective compliance plan. Rather, it will settle for good faith efforts by a medical practice to incorporate a culture of compliance and do as much as it can.

The OIG noted that it may not apply these more flexible standards to large group practices. It refers these practices to the guidance documents for billing companies and clinical laboratories for relevant information.

As noted above, the OIG acknowledges that full implementation of all seven components may not be feasible for all physician practices, and that some groups may never fully implement all of the components. The OIG suggests that, as a first step, physician practices can begin by adopting only those components which, based on a practice’s specific history with billing problems and other compliance issues, are most likely to provide an identifiable benefit.

V. DEVELOPING AN EFFECTIVE COMPLIANCE PROGRAM

The OIG believes that a basic framework for an effective compliance program begins with the following seven components, as set forth in previous OIG compliance program guidance and as adapted from the Federal Sentencing Guidelines:

- Perform baseline and periodic follow-up audits;
- Develop standards and procedures;
- Assign compliance officer or other contact person;
- Conduct training and education;
- Implement corrective action programs;
- Establish open lines of communication; and
- Take steps to enforce compliance program.
A. Auditing and Monitoring

The first step in developing an effective compliance plan is to determine whether the practice’s existing standards and procedures are current and accurate, and whether any existing compliance program is working. There are two types of reviews:

- Standards and Procedures Reviews. The OIG recommends that one or more individuals in the physician practice be charged with the responsibility of periodically reviewing the practice’s standards and procedures to determine if they are current and complete. Standards and procedures should be periodically updated to reflect changes in government regulations or compendiums generally relied upon by physicians and insurers.

- Claims Submission Audit. The OIG advises physician practices conduct a baseline audit of billing and medical records for compliance with the applicable coding, billing and documentation requirements. This initial audit should establish a baseline or “snapshot” against which the practice will judge its progress over time in reducing or eliminating potential areas of vulnerability. In particular, a baseline audit examines the practice’s claim development and submission process, and identifies elements within the process that may contribute to noncompliance or that may need to be improved. Following the baseline audit, periodic audits should be conducted at least once each year to ensure that the compliance program is being followed.

Ideally, according to the OIG’s compliance guidance, these audits should include the person in charge of billing and a physician or other medically trained person. Alternatively, the audit can be conducted by an independent consultant or other billing expert. A claims submission audit may be conducted retrospectively or concurrently with the claims submission. In general, the OIG suggests that claims submission audits can be used to determine whether bills are coded properly and accurately reflect the services provided, documentation is being completed correctly, services or items provided are reasonable and necessary, and any incentives for unnecessary services exist.

The OIG compliance guidance recommends that a physician practice develop a methodology for selecting and examining records for self-audits, and that the methodology be used consistently for future audits. The OIG did not provide a general rule for the sample size that should be used, but indicated that, as a basic guide, an audit of five or more medical records per federal payor (e.g., Medicare and Medicaid) or five to ten medical records per physician should be sufficient. If possible, both federal and private payor claims should be reviewed. The OIG also suggests that a practice that has identified risk areas or potential billing vulnerabilities may choose to conduct a targeted audit focusing on these issues.

In addition to auditing standards and procedures and claims submission practices, the group should review its contracts and transactions for compliance with Stark II and the federal Anti-Kickback statute. The audit should also review the effectiveness of the compliance program itself in identifying and resolving billing and coding problems. Further, the practice should require any billing companies with which it does business to be audited.

B. Written Standards and Procedures

In a significant change from other guidance documents, the OIG
indicated that physician practices need not adopt a written code of conduct. However, regardless of the practice’s size, a physician practice should develop a method for dealing with its areas of legal risk by preparing written standards and procedures. One approach for doing this is to focus first on those risk areas most likely to arise in the particular practice, as identified by the practice’s auditing and monitoring activities. The standards and procedures also should address issues raised by carrier updates, documentation guidelines, and OIG fraud alerts and advisory opinions.

As an alternative to developing its own written standards and procedures, a practice may adopt a third party’s compliance standards and procedures, such as those of a billing company, physician practice management company (PPMC), or a management services organization (MSO). The OIG also encourages physician practices to participate in other provider’s compliance programs, such as the compliance programs of hospitals or other settings in which the physicians practice. However, the practice should not blindly adopt the policies and procedures or participate in the compliance programs of others. It also should make sure that it is not unwittingly violating Stark II or the Medicare/Medicaid Anti-Kickback statute by accepting free items or services as an inducement for referrals. To avoid possible anti-kickback or self-referral issues, the OIG recommends that physicians consider limiting their participation in a sponsoring provider’s compliance program to the areas of training and education, or policies and procedures, and to pay fair market value for any items or services that it receives from an organization to which it makes referrals. When in doubt about the legality of such arrangements, the practice should consult with experienced legal counsel.

The OIG also suggests that practices create a resource manual of applicable laws, rules, and policies, as well as internal policies and guidelines. The OIG and HCFA intend to compile a list of basic documents issued by both agencies that could be included in such a binder, and will post the list on the OIG and HCFA websites (http://oig.hhs.gov/index.htm and http://www.hcfa.gov/, respectively).

The standards and procedures should be updated when necessary, and must be readily accessible to all employees. Any necessary updates to the standards and procedures should be promptly communicated to employees to keep them informed regarding the practice’s operations. Key personnel in the physician practice must be made aware of the risk areas applicable to their job task, and may need training specific to these risk areas.

1. **Identify Specific Risk Areas.**

The OIG believes that standards and procedures should address the following common risk areas for physician practices:

**Coding and Billing.** Coding and billing risk areas for physician practices include:

- 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 resulting in duplicate payment;
- Billing for non-covered services as if covered;
- Knowing misuse of provider identification numbers, which results in improper billing;
- Unbundling (billing for each component of the service instead of billing or using an all-inclusive code);
Failure to properly use coding modifiers;

Clustering (coding or charging one or two middle levels of service codes exclusively, under the philosophy that some will be higher, some lower, and the charges will average out over an extended period); and

Routinely upcoding the level of service provided

Coding and billing compliance standards should reflect the current reimbursement principles set forth in applicable statutes, regulations and federal, state or private payor health care program requirements. They should be developed in tandem with operational coding and billing standards used in the physician practice.

**Medically Reasonable and Necessary Services.** The OIG recognizes that physicians should be able to order any tests, including screening tests, they believe are appropriate for the treatment of their patients. However, Medicare will only pay, and a physician practice must only bill Medicare, for those services that are reasonable and necessary for the diagnosis and treatment of a patient. A physician practice can bill for services that it believes will be denied in order to receive a denial, but only if the denial is needed for reimbursement from a secondary payor. The practice’s billing records should contain documentation, such as medical records and physicians’ orders, to support the appropriateness of a service that the physician has provided.

**Documentation.** The OIG has indicated that one of the most important compliance issues for physician practices is the appropriate documentation of diagnosis and treatment. Specifically, a physician practice should maintain medical records that verify and document precisely what services were actually provided. The medical records may be used to validate the site of the service, the appropriateness of the services provided, the accuracy of the billing, and the identity of the provider of care. The OIG suggests the following specific documentation guidelines:

- Documentation should be complete and legible;
- Documentation should include the reason for the encounter, any relevant history, physical examination findings, prior diagnostic test results, assessments, clinical impressions, or diagnosis;
- Each patient's medical record should include a plan of care;
- **CPT and ICD-9 codes should be supported by documentation and the medical record; and**
- **Appropriate health risk factors should be identified.**

A practice may also want to craft specific procedures for certain records. For example, in preparing a CMS 1500 form, the billing personnel should link the diagnosis code with the reason for the visit or service, use modifiers appropriately, and provide Medicare with all information about a beneficiary's other insurance coverage under the Medicare Secondary Payor policy, if the practice is aware of a beneficiary's additional coverage.

**Improper Inducements, Kickbacks, and Self-Referrals.** The OIG is particularly concerned about improper arrangements between physician practices and hospitals, hospices, nursing facilities, home health agencies, durable medical equipment suppliers, pharmaceutical manufacturers and vendors. As a general rule, all business arrangements in which a physician practice refers business to, or orders services or items from, an outside entity should be evaluated to ensure that the transaction takes place at fair
market value. Similarly, physician practices should consider implementing measures to avoid offering inappropriate inducements to patients, such as 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.

The OIG has identified the following specific risk factors relating to inducements, kickbacks and self referrals: financial arrangements with outside entities to whom the practice may refer federal health care program business; joint ventures with entities supplying goods or services to the physician practice or its patients; consulting contracts or medical directorships; office and equipment leases with entities to which the physician refers; and soliciting, accepting or offering any gift or gratuity of more than nominal value to or from those who may benefit from a physician practice’s referral of federal health care program business, including, but not limited gifts from pharmaceutical companies. An effective physician practice compliance plan should address each of these issues, as well as any relevant OIG Special Fraud Alerts and Advisory Opinions that address the application of the anti-kickback and physician self-referral laws to the practice.

2. Develop Record Retention and Destruction Policy.

In addition to the development of policies and procedures relating to the applicable risk areas discussed above, a physician practice should document its record retention and destruction policy. The OIG has indicated that a physician practice should have procedures for maintenance of compliance, business and medical records, as well as documents relating to patient care and the practice’s business activities. The practice should also maintain records of educational activities, compliance efforts, internal investigations and internal audit results.

In particular, the practice should document investigations of potential violations uncovered by the compliance program and the resulting remedial action taken. The OIG specifically stated that such documentation would benefit the practice should it ever be questioned regarding those activities. The OIG also believes that a practice would be well advised, to the extent it is possible, to document its efforts to comply with applicable federal health care program requirements, including any advice the practice receives from a government agency or Medicare carrier.

In developing standards and procedures relating to the creation, distribution, retention and destruction of documents, a practice should be mindful of any privacy concerns and federal or state regulatory requirements applicable to record retention, including the final patient privacy regulations issued under the federal Health Insurance Portability and Accountability Act of 1996.

The OIG suggests that a physician practice consider the following specific guidelines for its record retention policy:

- Specify the length of time that a practice’s records are to be retained;
- Secure medical records against loss, destruction, unauthorized access, unauthorized reproduction, corruption, or damage; and
- Stipulate the disposition of medical records in the event the practice is sold or closed.


The OIG recommends that physician practices also adopt
procedures for monitoring the acts of their billing companies and other agents and for screening prospective employees and suppliers. The agency suggests that practices consult the OIG’s list of excluded entities and the General Services Administration’s (“GSA”) List of Parties Debarred from Federal Programs before hiring or doing business with any other entities that do business with Medicare.

C. Designation of a Compliance Officer or Contacts

The OIG suggests that one member of a group’s staff should take on the role of compliance officer. In addition to duties relating generally to overseeing the compliance plan, this individual would accept the responsibility of developing a corrective action plan, if necessary to address any risk factors or actual problems, and oversee the practice’s adherence to that plan. The OIG realizes that physician practices may be unable to justify designating one person to be in charge of compliance functions. In the alternative, it is acceptable for a physician practice to designate more than one employee with compliance monitoring responsibility. For example, the practice could designate certain employees (“compliance contacts”) to be responsible for specific compliance areas or appoint a compliance committee.

Instead of a single compliance officer for a single practice, the OIG indicates that one individual could serve as compliance officer for more than one entity, or that the practice could outsource all or part of the functions of a compliance officer to a third party, such as a consultant, PPMC, MSO, IPA or third-party billing company. If, however, this role is outsourced, it is important for the compliance officer to closely interact with the physician group to be able to effectively understand the inner workings of the practice. Consultants that are not in close geographic proximity to a practice, according to the OIG guidance, may not be effective compliance.

The OIG provided the following list of suggested duties for a compliance officer or compliance contact:

- Overseeing and monitoring the implementation of the compliance program;
- Establishing methods, such as periodic audits, to improve the practice’s efficiency and quality of services, and to reduce the practice’s vulnerability to fraud and abuse;
- Periodically revising the compliance program in light of changes in the needs of the practice or changes in the law and in the standards and procedures of Government and private payor health plans;
- Developing, coordinating and participating in a training program that focuses on the components of the compliance program, and seeks to ensure that training materials are appropriate;
- Ensuring that the OIG’s List of Excluded Individuals and Entities, and the GSA’s List of Parties Debarred from Federal Programs have been checked with respect to all employees, medical staff and independent contractors; and
- Investigating any report or allegation concerning possible unethical or improper business practices, and monitoring subsequent corrective action or compliance.

Each practice must assess its own situation and determine what degree of compliance oversight best suits the group.

D. Conducting Appropriate Training and Education

The OIG compliance guidance recognizes that the economics of
each physician practice will affect the form and frequency of training and education. Thus, where possible, education programs should be tailored to fit the physician practice's needs, specialty and size, and should include both compliance and specific training. At a minimum, the practice must find an effective way to communicate its compliance standards, policies, and procedures to everyone in the practice.

The OIG compliance guidance identifies three threshold steps involved in the training and education phase:

- Determining who needs training (both in coding and billing and in compliance)
- Determining the type of training that best suits the practice's needs; and
- Determining when and how often training is needed and how much each person should receive.

Training can take many shapes, including in-person training sessions, distribution of newsletters, or even posting training materials on a readily-accessible office bulletin board. No matter what form of training the physician practice uses, it should ensure that the necessary education is communicated effectively and that the practice's employees come away from the training with a better understanding of the issues covered.

The OIG compliance guidance contemplates the following two general categories of training applicable to preventing health care fraud and abuse and preventing errors in the submission of claims:

- **Compliance Training.** This category includes discussion of the operation and importance of the compliance program, the consequences of violating the standards and procedures set forth in the program, and the role of each employee in the operation of the compliance program. Both initial (e.g., upon hiring) and recurrent (e.g., at least annual) training in compliance is advisable. The OIG identified two goals for compliance training: (1) All employees will receive training on how to perform their jobs in compliance with the standards of the practice and any applicable regulations; and (2) each employee will understand that compliance is a condition of continued employment. In addition, compliance training should emphasize that following the standards and procedures will not get a practice employee in trouble, but violating the standards and procedures may subject the employee to disciplinary measures.

- **Coding and Billing Training.** The OIG also suggests that certain members of the practice's staff should receive specialized training depending on their respective responsibilities. The guidance document indicates that it is in the practice's best interest to ensure that individuals who are directly involved with billing, coding or other aspects of the federal health care programs receive extensive education specific to that individual's responsibilities as soon as possible after hiring and at least annually thereafter. Examples of information to be communicated in coding and billing training include coding requirements; claim development and submission processes; authorization protocols; proper documentation of services rendered; proper billing standards and procedures and submission of accurate bills for services or items rendered to federal health care program beneficiaries; and legal sanctions for submitting deliberately false or reckless billings.

A physician practice may conduct training in-house or through the use of an outside source (e.g., community colleges, professional associations, Medicare carriers).
A practice may also choose to work with its third-party billing company to ensure that documentation is sufficiently detailed and legible so the billing company can submit accurate claims on behalf of the physician practice. The OIG indicated that it is advisable for physician practices to maintain updated ICD-9, HCPCS and CPT manuals (including carrier bulletins) and make them available to all employees involved in the billing process.

**E. Responding To Detected Offenses and Developing Corrective Action Initiatives**

The OIG lists several warning signs for physician practices:

- Significant changes in the number and/or types of claim rejections and/or reductions;
- Correspondence from carriers and insurers challenging medical necessity or validity of claims;
- Illogical patterns or unusual changes in the pattern of CPT4, HCPCS or ICD9 code utilization; and
- High volumes of unusual charge or payment adjustment transactions.

In the event that the practice detects a violation, the practice’s compliance procedures may need to be changed to prevent the problem from recurring. If a practice identifies a violation of law, the OIG indicates that the practice would be well-advised to include steps for prompt referral or disclosure to an appropriate government authority or law enforcement agency. This is particularly important, due to the fact that criminal sanctions may apply to a failure to report such violations. In addition, the OIG indicated that a practice that identifies overpayment issues should take appropriate corrective action, including prompt identification and repayment of any overpayment to the affected payor.

The OIG has established voluntary disclosure protocols that may lead to more lenient treatment of the disclosing practice. However, the protocols provide no guarantees that legal action will not be taken against the disclosing party. Therefore, a practice should seek the guidance of an attorney before engaging in voluntary disclosure or otherwise indicating to the government that the practice may have had a lapse in its internal controls.

The OIG also recommends that a practice’s compliance program should provide for a full internal assessment of all reports of detected violations. Furthermore, the compliance program standards and procedures should include provisions to ensure that a violation is not compounded once discovered. As part of the resolution of a violation, the practice must determine whether the individuals involved should be retrained, disciplined, or, if appropriate, terminated.

**F. Developing Open Lines of Communication**

Compliance guidance documents previously issued by the OIG have encouraged the use of
several forms of communication between the compliance officer (or other compliance contacts) and provider personnel. The OIG recognizes, however, that the nature of some physician practices is not conducive to implementing elaborate communication measures. For some physician practices, a less formalized process may be appropriate. Suggestions for any policy, however, include the following:

- Management and compliance contacts should maintain an "open door" policy;
- Conspicuous compliance notices should be posted in common areas;
- The practice may want to develop a compliance bulletin;
- The standards and procedures should indicate that employees are required to report conduct that a reasonable person would, in good faith, believe to be erroneous or fraudulent, but that there will be no retribution for such good faith reporting;
- The practice should implement a user-friendly process (e.g., an anonymous drop box for larger practices) for effectively reporting erroneous or fraudulent conduct;
- The compliance plan should include statements in the standards and procedures that a failure to report erroneous or fraudulent conduct is a violation of the compliance program;
- The practice should develop a simple and readily accessible procedure to process reports of erroneous or fraudulent conduct;
- If a billing company is used, the practice must maintain communication to and from the billing company's compliance officer or contact and other responsible staff to coordinate billing and compliance activities of both the practice and the billing company; and
- If feasible, the practice should utilize a process that maintains the anonymity of the persons involved in the reported possible erroneous or fraudulent conduct and the person reporting the concern.

The OIG recognizes that protecting the anonymity of an employee reporting a violation may not be feasible for small physician practices. All practice employees, however, should know to whom to turn for assistance in these matters and should be able to do so without fear of retaliation.

G. Enforcing Disciplinary Standards Through Well-Publicized Guidelines

A practice should implement measures to ensure that its employees understand the consequences if they behave in a noncompliant manner. In addition, the compliance plan should include procedures for enforcing and disciplining individuals who violate the practice's compliance or other practice standards. Such enforcement and discipline, according to the OIG, adds credibility and integrity to a compliance program.

The OIG indicates that a practice’s compliance program should ensure that violations of the practice’s compliance policies, including failure to report violations, will result in consistent, fair, and appropriate sanctions, such as oral warnings, written reprimands, probation, demotion, temporary suspension, termination, restitution of damages, and referral for criminal prosecution. These policies should be integrated with the practices of other employment policies and should be included in the practice’s training manuals. The OIG advises, however, that the practice’s enforcement and disciplinary procedures be flexible enough to account for mitigating or aggravating circumstances.
The compliance guidance document further suggests that any communication resulting in the finding of noncompliant conduct should be documented in the compliance files by including the date of incident, name of the reporting party, name of the person responsible for taking action, and the follow-up action taken.

III. CONCLUSION

Effective compliance plans for individual and small group physician practices will not be "off-the-shelf" or "one-size-fits-all" solutions. Instead, each practice must tailor a compliance plan that fits the circumstances of that group. The OIG compliance guidance indicates that the adoption of a compliance plan is strictly voluntary, and that each practice needs to evaluate a variety of factors, including economic constraints, in undertaking such a plan. A physician practice that has no formal compliance plan should nonetheless adhere to sound compliance principles. As a general rule, a physician practice will be better off with a compliance plan than without one, as long as the plan is effective.

By contrast, a compliance plan that is not followed, or that is largely ineffective, may be worse than no compliance plan at all.

The information presented here is not intended to be legal advice. Instead, it is designed to be educational and illustrative. The laws and regulations in this area are changing on a daily basis, making it essential that medical practices keep up with these rapidly changing rules. Individual medical practices should consult with legal counsel and other experts in developing or improving their own compliance programs. Significantly, this document addresses only federal billing and fraud and abuse rules. It does not touch on state law or the numerous other federal laws and regulations affecting medical practices (e.g., patient privacy, employment, tax, antitrust, health and safety).

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