

CORPORATE ETHICS AND GOVERNANCE IN THE HEALTH CARE MARKETPLACE
CONFERENCE: AN INTERDISCIPLINARY DISCUSSION

PANEL DISCUSSION

CORPORATE ACCOUNTABILITY AND COMPLIANCE IN HEALTH CARE:
WILL HEALTH CARE BE THE NEXT ENRON?

February 27, 2004

Kimberly D. Baker
Arisa M. Peterson

Williams, Kastner & Gibbs, PLLC
Two Union Square
601 Union Street, Suite 4100
P.O. Box 21926
Seattle, WA 98111-3926
Main: (206) 628-6600
FAX: (206) 628-6611
kbaker@wkg.com
apeterson@wkg.com

Kim Baker is a member of the Seattle office of Williams, Kastner & Gibbs, PLLC. She combines her former experience as a health care provider with her many years of practice to successfully defend health care claims relating to medical negligence, regulatory and licensing issues and medical drug and device litigation. Kim represents clients dealing with many of challenging issues arising in the employment arena , including discrimination and harassment claims. She has processed claims under and lectured on the Sarbanes-Oxley Act. She is recognized for her experience and leadership by being selected to serve as the past vice program chair and current program chair of the Defense Research Institute "DRI" Medical Liability and Health Care Law Seminar . She is active in the medical, employment and white collar crime sections of the DRI and the Federation of Defense and Corporate Counsel. As a frequent lecturer and author, she offers practical tips on topics , such as executive witness preparation and jury selection in a punitive damages case. Her nursing and law degrees were obtained from the University of Kansas.

Ariisa Peterson is an associate in the Seattle office of Williams, Kastner & Gibbs, PLLC. Her practice focuses on civil and commercial litigation with an emphasis in health care law and product liability defense, including pharmaceutical and medical negligence cases. Ms. Peterson is a member of the Health Care Section of Washington State Bar Association and a member of the Washington Defense Trial Lawyers Association. She received her J.D. from University of Oregon. Prior to receiving her law degree, she worked as an administrator for a residency and medical student education program.

CORPORATE COMPLIANCE AND ACCOUNTABILITY IN THE HEALTH CARE PROVIDER AND PHARMACEUTICAL INDUSTRIES: MITIGATING FRAUD, WASTE AND ABUSE

INTRODUCTION

In recent years, the government has devoted substantial resources to respond to health care fraud and abuse. The increase in governmental prosecutorial activity in the health care industry can be traced to two significant trends. Concern over waste, fraud and abuse has become more prevalent, prompting the Department of Justice to identify the eradication of health care fraud as its number two priority, right behind violent crime.¹ In addition, employees are becoming increasingly aware of the economic benefits of becoming a “whistleblower.”² The *qui tam* provisions of the False Claims Act entitles individuals who bring violations of the Act to the attention of the government to a significant percentage of any recovery.³

The Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”) is encouraging the health care community to prevent and reduce fraud and abuse in federal health care programs by providing voluntary guidance on effectively implementing and monitoring a compliance program. In the last several years, the OIG has issued compliance program guidance directed at several segments of the health care industry. The best way for a health care organization to mitigate risk is to implement an effective compliance program.

This paper will address the myriad of federal and state statutes regulating health care fraud and abuse, delineating certain risk behaviors targeted by these statutes, and analyzing the

¹ See generally Paul E. Kalb, MD & I. Scott Bass, Government Investigations in the Pharmaceutical Industry: Off-Label Promotion, Fraud and Abuse, and False Claims, 53 FOOD DRUG L.J. 63 (1998).

² Id.

³ 31 U.S.C. § 3730(d)

penalties associated with unlawful conduct. The second part of this paper will discuss the importance of implementing a comprehensive and effective compliance program for hospital organizations and the pharmaceutical manufacturing industry. Finally, this paper will address the overall impact of the heightened scrutiny of the health care industry, including recommended reform measures.

I. OVERVIEW OF STATUTORY SCHEMES REGULATING FRAUD AND ABUSE

A. Introduction.

There are a multitude of Federal statutory schemes aimed at preventing waste, fraud and abuse in the health care industry. The prime areas of governmental concern include:

1. Additional costs to Federal health care programs;
2. Quality of care;
3. Access to care;
4. Patients' freedom of choice;
5. Competition; and
6. Health care providers abuse of professional judgment.

A common thread running through each of the federal statutes is that the bottom line is always about money—wrongful receipt of state or Federal funds, the presentment of a false claim for reimbursement, or improper relationships with referral sources (resulting in kickbacks/discounts). Many of the statutory schemes impose criminal as well as stiff civil penalties.

The government's enforcement efforts have resulted in a multi-billion dollar recovery. In 2003 alone, over \$2 billion was recovered. In fiscal year 2003, whistle-blowers recovered over

\$319 million in rewards under the Act. Between 1995 and 2003, over \$8 billion has been recovered. Six billion dollars has been recovered as a result of whistleblower cases.⁴

On a local level, the University of Washington Medical Center was the subject of investigation for Medicare and Medicaid billing fraud resulting from the report of a whistleblower who worked in the billing and compliance section of the UW's billing groups. Allegedly, the UW submitted millions of dollars worth of faulty medical insurance reimbursement claims from 1996 to 2002. Criminal charges were brought against two physicians, both of whom entered into plea arrangements, but no other individual university officials were charged. The UW faculty members were the first two faculty members in the U.S. to be convicted of criminal Medicare fraud.

The following is a sample of the DOJ's largest recoveries during 2003 for fraud and abuse in health care:

- \$641 million from HCA Inc. (formerly known as Columbia/HCA and HCA - The Healthcare Company) for cost report fraud, the payment of kickbacks to physicians and overbilling Medicare for HCA's wound care centers. This settlement concluded litigation in numerous qui tam lawsuits as well as separate investigations initiated by the government. Along with an earlier civil settlement and criminal guilty plea reached in 2000, as well as a related administrative settlement with HHS, HCA has paid the United States \$1.7 billion, with whistleblowers receiving a combined share of \$154 million-by far, setting record recoveries both by the United States and whistle-blowers.

- \$382 million from Abbott Laboratories and its Ross Products Division. Abbott's conduct resulted in the first combined civil settlement and criminal conviction arising from "Operation Headwaters," an undercover investigation by the Federal Bureau of Investigation, the U.S. Postal Inspection Service and the Office of the Inspector General for HHS, in which federal agents created a fictitious medical supplier known as Southern Medical Distributors. During its operation, various manufacturers, including Ross, offered kickbacks to undercover agents to purchase the manufacturers' products and then advised them how to fraudulently bill the government for those items. In addition to federal Medicare and Medicaid recoveries, the states

⁴ Department of Justice Press Release November 10, 2003, Justice Dept. Civil Fraud Recoveries Total \$2.1 Billion For FY 2003 False Claims Act Recoveries Exceed \$12 Billion Since 1986.

recovered \$18 million in state Medicaid funds in connection with the federal government's claims and an additional \$14.5 million on claims the states pursued alone. Abbott subsidiary C G Nutritionals also paid \$200 million in criminal fines.

-\$280 million from AstraZeneca Pharmaceuticals, LP, to resolve allegations that AstraZeneca conspired with health care providers to charge Medicare, Medicaid and other federally funded insurance programs for free samples of its prostate cancer drug, Zoladex, and for otherwise inflating the price of the drug in violation of the Prescription Drug Marketing Act. The whistleblower's share of this settlement was \$47.7 million.

-\$143 million from Bayer Corporation to resolve a whistleblower's allegations that Bayer defrauded the Medicaid and Public Health Service programs by relabeling products sold to a health maintenance organization at deeply discounted rates and then concealing the discounts to avoid paying rebates, in violation of the Medicaid Rebate program. In addition, Bayer paid \$108 million to reimburse state Medicaid programs for the same conduct.

-\$47 million from SmithKline Beecham Corporation, doing business as GlaxoSmithKline, to settle claims similar to those against Bayer. GlaxoSmithKline paid an additional \$40 million to reimburse state Medicaid programs and Public Health Service entities.

-\$51 million from Tenet Healthcare Corporation and Tenet HealthSystems Hospitals, Inc. to settle government allegations that Tenet's Redding, California facility performed unnecessary cardiac procedures that were then billed to Medicare, Medicaid and TRICARE. In addition, Tenet paid nearly \$3 million to reimburse California's Medicaid funds.

-\$49 million from Endovascular Technologies, Inc., a subsidiary of Guidant Corp., to settle the government's allegations that Endovascular Technologies failed to report to the Food and Drug Administration thousands of adverse incidents involving its "Ancure" cardiac device. The failure resulted in the submission of tens of millions of dollars of false claims for Medicare, Medicaid and VA benefits for procedures involving the device. In several instances, the device was linked to patient injuries and deaths. Endovascular Technologies also paid \$43.4 million in criminal fines and forfeitures.⁵

The net result of the increased focus on health care fraud and abuse is that organizations must understand the structures and regulations and how to avoid or, at a minimum, mitigate risks.

B. False Claims Act.

The Civil False Claims Act, 31 U.S.C. §§ 3729-3733, ("FCA") a Civil War-era statute, prohibits the knowing submission of false or fraudulent claims to the federal government. The

⁵ Id.

FCA was not originally enacted to address health care fraud. Nonetheless, FCA is the legal basis most often used to bring a case against a health care provider for the submission of false claims to a Federal health care program. Numerous other fraud statutes are tied to the FCA.

The FCA prohibits knowingly presenting (or causing to be presented) to the Federal Government a false or fraudulent claim for payment or approval. Additionally, it prohibits knowingly making or using (or causing to be made or used) a false record or statement to get a false or fraudulent claim paid or approved by the Federal Government or its agents, like a carrier, other claims processor, or State Medicaid program.

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; or
- 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. An example of a provider who submits a false claim with deliberate ignorance would be a physician who ignores provider update bulletins and thus does not inform his/her staff of changes in the Medicare billing guidelines or update his/her billing system in accordance with changes to the Medicare billing practices. When claims for non-reimbursable services are submitted as a result, the False Claims Act has been violated.

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

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

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

-Dr. X, a podiatrist, knowingly submitted claims to the Medicare and Medicaid programs for non-routine surgical procedures when he actually performed routine, non-covered services such as the cutting and trimming of toenails and the removal of corns and calluses.

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

The FCA has become a powerful tool for uncovering fraud and abuse of government programs. One unique feature is FCA's *qui tam* provisions, which provide a mechanism for private citizens and their attorneys to blow the whistle on private parties who defraud government programs. The FCA compensates the private whistleblower if his or her efforts are successful in helping the government recover fraudulently obtained government funds.

The 1986 Amendments added *qui tam* provisions that:

1. Entitle successful whistleblowers to at least 15% and up to 30% of the funds they help the government recover from the defendant;
2. Provide that the defendant pay for the successful whistleblowers reasonable expenses and attorney's fees;
3. Protect whistleblowers from employer retaliation; and
4. Allow whistleblowers and the lawyers to remain as parties in the suits even after the Government joins;

The FCA's *qui tam* provisions allow a private person to bring a lawsuit on behalf of the United States Government.⁶ The private person must have non-public information of the fraud (unless they qualify as an "original source" of the information, in which case the percentage of recovery available is reduced).⁷ This jurisdictional bar (referred to as the "public disclosure" provision) effectuates the FCA's purpose in encouraging only those *qui tam* suits that actually alert the Government to fraud.

Likewise, the private person must also be the first-to-file the lawsuit.⁸ This "first-to-file" rule of the FCA is heavily-litigated. Disputes commonly arise where two lawsuits allege the same fraud against different defendants (even related companies) or where the two lawsuits allege a slightly different fraud against the same defendant.

The FCA contains an anti-retaliation provision for the protection of relators.⁹ Under § 3730(h), any employee who is fired, demoted, harassed or otherwise discriminated against because of lawful acts "in furtherance of" a *qui tam* action is entitled to all relief necessary to

⁶ 31 U.S.C. § 3730(b).

⁷ 31 U.S.C. §3730(e)(4)(A).

⁸ 31 U.S.C. § 3730(b)(5).

⁹ 31 U.S.C. § 3730(h).

make the employee whole. This may include reinstatement, twice the amount of back pay, and payment of litigation costs and attorneys' fees.

In addition to section 3730(h) of the FCA, many states have laws that may protect a *qui tam* relator from employment retaliation for reporting or refusing to participate in fraud.

C. Sarbanes-Oxley Act¹⁰

The Sarbanes-Oxley Act was signed into law on July 30, 2002 in response to corporate scandals including Arthur Andersen's indictment and conviction for obstructing justice by shredding accounting documents after the investigation into Enron's implosion, and WorldCom's June 2002 announcement that it had overstated its earnings for five previous quarters by over \$3.8 billion, among others. The stated purpose of the Act is to "protect investors by improving the accuracy and reliability of corporate disclosures made pursuant to the securities laws, and for other purposes." This law will require a Public Company Accounting Oversight Board to oversee public companies' financial statement audits through rigorous registration, standard setting, inspection and disciplinary programs. The Act also promulgates proposed regulations for corporate conduct, including, but not limited to, regulations concerning accounting, corporate governance, public disclosures, and "whistle-blower" protections.

1. Whistleblower Provisions Under Sarbanes-Oxley.

Section 806 of the Sarbanes-Oxley Act creates federal protection for whistleblowers who work for publicly traded companies. Section 806 amends 18 § U.S.C. by adding Section 1514A which prohibits retaliatory conduct toward anyone who participates in lawful reporting of violations concerning financially fraudulent company activities. In order to receive protection

¹⁰ Portions of the Sarbanes-Oxley section are modified from the article, *When the Whistle Blows – You Better Stop, Listen and Investigate*, by Kimberly D. Baker and Rashelle C. Tanner.

under this statute, the whistleblower must reasonably believe that the activities constitute violations of (a) federal securities law, (b) SEC rules or regulations or (c) other federal law provisions that relate to shareholder fraud.

Two of the key elements are reporting and individual liability. To warrant protection under Sarbanes-Oxley, the alleged violations must be reported to a law enforcement officer or to someone with supervisory authority or authority to investigate, discover or correct the violations. Unlike Title VII, this new legislation permits remedies against *individual actors* as well as the company. The broader classes of people who may be individually liable include officers, employees of publicly traded corporations, and corporate contractors, sub-contractors, and agents.

This legislation is the most protective measure to protect shareholders from similar losses resulting from Enron and WorldCom abuses. However, the Act's new protections must be balanced with employer vulnerability to significant civil and criminal penalties. Corporations must now implement and facilitate constructive whistle blowing procedures or risk considerable exposure to litigation, fines and other criminal penalties.

The Sarbanes-Oxley whistleblower provisions are distinguishable from traditional whistleblower employment retaliation statutes as Sarbanes-Oxley imposes criminal penalties for acts of retaliation. Section 1107 of the Act provides that **any individual who knowingly, with the intent to retaliate, takes harmful action against a person who provides truthful information to a law enforcement officer, regarding a commission of any federal offense will be fined and/or subjected to up to ten years imprisonment.** Publicly traded companies and their individual officers, managers and agents must use more caution when terminating, demoting or taking other adverse employment actions against their employees.

The breadth of individuals who may be liable under the Act is expansive, including any officer, employee, contractor, subcontractor or agent of the company. Vicarious liability also arises from these actors' conduct. Outside corporate legal counsel will likely be included in the cast of eligible defendants.

A complaint of retaliation may arise if any of the above actors engage in the following retaliatory conduct: discharge, demote, suspend, threaten, harass or in any way discriminate against an employee in the terms and conditions of employment. While "terms and conditions" are not defined, it is reasonable to consider that the court may analogize it to the definition of "tangible employment action" as stated by the U.S. Supreme Court in *Burlington Industries, Inc. v. Ellerth*, 118 S. Ct. 2257, 77 FEP 1 (1998). The definition adopted by the court was "a tangible employment action constitutes a significant change in employment status, such as hiring, firing, failing to promote, reassignment with significantly different responsibilities, or a decision causing a significant change in benefits."

Under the Act, employers are required to both establish audit committees and adopt procedures for the confidential and anonymous reporting of concerns regarding questionable accounting or auditing practices. Public L. No. 107-204, Sec. 301 amending 5 U.S.C. Sec 78(f). In light of the risks created by the Act's whistleblower provisions, corporations should establish an unbiased external audit committee for the confidential reporting of retaliation.

2. Retaliation Damages under Sarbanes-Oxley.

Sarbanes-Oxley provides for reinstatement, back pay with interest, and compensatory damages. Compensatory damages include reasonable attorneys' fees and costs if the whistleblower prevails. The Act does not provide for punitive damages. Judicial review is only

available through the Court of Appeals, but such appeal does not automatically stay the Department of Labor's order.¹¹ Importantly, the Act does not preempt or supplant existing state law or collective bargaining agreement protections for whistleblowers, including tort actions for wrongful termination in violation of public policy (for which emotional distress and punitive damages against the employer are available). Employees may also recover damages for intangible harms such as being ostracized, ridiculed or harassed. Remedies under state law and collective bargaining agreements are not preempted.¹²

The Act specifically delineates the type of conduct that warrants protection. First, disclosing information or assisting in an investigation based on the employee's reasonable belief that there has been a violation of federal mail fraud, wire fraud, securities law fraud, bank fraud or any violation of SEC or federal laws prohibiting fraud against shareholders. Disclosures of this nature are protected if they are made to a person with supervisory authority over the employee, a federal regulatory or law enforcement agency, congress or an investigation agency hired by the employer to investigate matters of suspected violations. Second, protected conduct also includes filing or participating in a proceeding involving allegations of the above violations. These types of conduct are akin to the "opposition" and "participation" activity protected by Title VII.

Significantly, Section 1107 (18 U.S.C. Sec. 1513(e)), the criminal penalties section is applicable only when the whistleblower provides truthful information to a law enforcement officer. However, unlike Section 806, the criminal penalty provisions consider intentional retaliation to be "any action harmful to any person" who reported "any federal offense."

¹¹ See Senate Report No. 107-146.

¹² 18 U.S.C.A. § 1514A (d).

D. Criminal Penalties for Acts Involving Federal Health Care Programs under 42 U.S.C. § § 1320a-7b.

1. False Statement and Representations

It is a crime to knowingly and willfully:

- (1) make, or cause to be made, false statements or representations in applying for benefits or payments under all Federal health care programs;
- (2) make, or cause to be made, any false statement or representation for use in determining rights to such benefit or payment;
- (3) 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;
- (4) convert a benefit or payment to a use other than for the use and benefit of the person for whom it was intended;
- (5) present, or cause to be presented, a claim for a physician's service when the service was not furnished by a licensed physician;
- (6) 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.

2. Anti-Kickback Statute

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

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

The statute prohibits the solicitation or receipt of any remuneration for a prohibited purpose, which places both parties to a prohibited “kickback” transaction at equal risk.¹³

The statute covers transactions involving any of the federal health programs.¹⁴

The statute requires intent; therefore, paying money or transferring value is not illegal as long as it is not done with improper intent (“knowingly and willfully . . . to induce”). The precise meaning of “knowing and willful” varies among jurisdictions. The Ninth Circuit has held that to prove that an “inducement” is “knowing and willful,” the government must prove that the defendant knew that the Anti-Kickback statute “prohibits offering or paying remuneration to induce referrals” and that the defendant engaged in the “prohibited conduct with the specific intent to disobey the law.” Hanlester Network v. Shalala, 51 F.3d 1390 (9th Cir. 1995). Other courts have found a lesser mens rea is required. See United States v. Jain, 93 F.3d 436 (8th Cir. 1996).

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

Current safe harbors include:

- investment interests;
- space rental;
- equipment rental;
- personal services and management contracts;
- sale of practice;

¹³ 42 U.S.C. § 1320a-7b(b)(1)(B).

¹⁴ Health Insurance Portability and Accountability Act, Pub. L. No. 104-191, § 204, 110 Stat. 1936, 1999 (1996).

- referral services;
- warranties;
- discounts;
- employment relationships;
- waiver of Part A co-insurance and deductible amounts;
- group purchasing organizations;
- increased coverage or reduced cost sharing under a risk-basis or prepaid plan;
and
- charge reduction agreements with health plans.

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

Examples

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

E. Patient Anti-Dumping Statute.

The patient anti-dumping statute, 42 U.S.C. § 1395dd, requires that all Medicare participating hospitals with an emergency department: (1) Provide for an appropriate medical screening examination to determine whether or not an individual requesting such examination has an emergency medical condition; and (2) if the person has such a condition, (a) stabilize that condition; or (b) appropriately transfer the patient to another hospital.

F. Health Care Fraud under 18 U.S.C. § 1347.

Under 18 U.S.C. § 1347,

It is a crime to knowingly and willfully execute (or attempt to execute) a scheme to defraud any health care benefit program, or to obtain money or property from a health care benefit program through 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.

The penalty may include the imposition of fines, imprisonment of up to 10 years, or both.

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

Examples

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

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

G. Theft or Embezzlement in Connection with Health Care under 18 U.S.C. § 669.

Under 18 U.S.C. § 669,

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.

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

Example

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

H. False Statements Relating to Health Care Matters under 18 U.S.C. § 1035.

Under 18 U.S.C. § 1035,

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.

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

Example

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

I. Obstruction of Criminal Investigation of Health Care Offenses under 18 U.S.C. § 1518.

Under 18 U.S.C. § 1518,

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

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

Examples

1. Dr. X instructs his employees to tell OIG investigators that Dr. X personally performs all treatments when, in fact, medical technicians do the majority of the treatment and Dr. X is rarely present in the office.

2. Dr. X was under investigation by the FBI for reported fraudulent billings. Dr. X altered patient records in an attempt to cover up the improprieties.

J. Mail and Wire Fraud under 18 U.S.C. §§ 1341 and 1343.

Under 18 U.S.C. §§ 1341 and 1343,

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.

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

Examples

1. Dr. X knowingly and repeatedly submits electronic claims to the Medicare carrier for office visits that he did not actually provide to Medicare beneficiaries with the intent to obtain payments from Medicare for services he never performed.

2. Dr. X, a neurologist, knowingly submitted claims for tests that were not reasonable and necessary and intentionally upcoded office visits and electromyograms to Medicare.

K. Civil Monetary Penalties Law under 42 U.S.C. §§ 1320a-7a.

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; or

-furnished by a physician who was excluded from participation in the Federal health care program to which the claim was submitted.

Additionally, the CMPL contains various other prohibitions, including:

-offering remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary to obtain items or services billed to Medicare or Medicaid from a particular provider;

-employing or contracting with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program.

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

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

Examples

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

2. Dr. X hired Physician Assistant P to provide services to Medicare and Medicaid beneficiaries without conducting a background check on P. Had Dr. X

performed a background check by reviewing the HHS-OIG List of Excluded Individuals/Entities, Dr. X would have discovered that he should not hire P because P is excluded from participation in Federal health care programs for a period of 5 years.

3. Dr. X and his oximetry company billed Medicare for pulse oximetry that they knew they did not perform and services that had been intentionally upcoded.

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

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

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

Exceptions for Ownership or Compensation Arrangements

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

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

-ownership of investment securities which may be purchased on terms generally available to the public;

-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 3 fiscal years, total assets exceeding \$ 75,000,000;

-hospital in Puerto Rico;

-rural provider; and

-hospital ownership (whole hospital exception).

Exceptions Relating to Other Compensation Arrangements

-rental of office space and rental of equipment;

-bona fide employment relationship;

-personal service arrangement;

-remuneration unrelated to the provision of designated health services;

-physician recruitment;

-isolated transactions;

-certain group practice arrangements with a hospital (pre-1989); and

-payments by a physician for items and services.

Violations of the statute subject the billing entity to denial of payment for the designated health services, refund of amounts collected from improperly submitted claims, and a civil monetary penalty of up to \$ 15,000 for each improper claim submitted. Physicians who violate the statute may also be subject to additional fines per prohibited referral. In addition, providers

that enter into an arrangement that they know or should know circumvents the referral restriction law may be subject to a civil monetary penalty of up to \$ 100,000 per arrangement.

Examples

1. Dr. A worked in a medical clinic located in a major city. She also owned a free standing laboratory located in a major city. Dr. A referred all orders for laboratory tests on her patients to the laboratory she owned.

2. Dr. X agreed to serve as the Medical Director of Home Health Agency, HHA, for which he was paid a sum substantially above the fair market value for his services. In return, Dr. X routinely referred his Medicare and Medicaid patients to HHA for home health services.

3. Dr. Y received a monthly stipend of \$ 500 from a local hospital to assist him in meeting practice expenses. Dr. Y performed no specific service for the stipend and had no obligation to repay the hospital. Dr. Y referred patients to the hospital for in-patient surgery.

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

Individuals or entities convicted of the following conduct must be excluded from participation in Medicare and Medicaid for a minimum of 5 years:

(1) a criminal offense related to the delivery of an item or service under Medicare or Medicaid;

(2) a conviction under Federal or State law of a criminal offense relating to the neglect or abuse of a patient;

(3) 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;

(4) a conviction under Federal or State law of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

If there is one prior conviction, the exclusion will be for 10 years. If there are two prior convictions, the exclusion will be permanent.

Permissive Exclusion

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

(1) a criminal offense related to the delivery of an item or service under Medicare or Medicaid;

(2) 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;

(3) interference with, or obstruction of, any investigation into certain criminal offenses;

(4) a misdemeanor related to the unlawful manufacture, distribution, prescription or dispensing of a controlled substance;

(5) exclusion or suspension under a Federal or State health care program;

(6) 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;

(7) violating the Civil Monetary Penalties Law or the statute entitled "Criminal Penalties for Acts Involving Federal Health Care Programs;"

(8) 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);

(9) failure to disclose information required by law;

(10) failure to supply claims payment information; and

(11) defaulting on health education loan or scholarship obligations.

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

Examples

1. Nurse R was excluded based on a conviction involving obtaining dangerous drugs by forgery. She also altered prescriptions that were given for her own health problems before she presented them to the pharmacist to be filled.

2. Practice T was excluded due to its affiliation with its excluded owner. The practice owner, excluded from participation in the Federal health care programs for soliciting and receiving illegal kickbacks, was still participating in the day-to-day operations of the practice after his exclusion was effective.

N. Washington State Statutes.

1. RCW 48.30A.

RCW 48.30A is the Health Insurance Fraud Act. With some limited exceptions contained in RCW 48.30A.020, in relevant part, for attorney-doctor payments for services rendered or expert witness fees, minor gratuities, group buying exceptions or multi-provider advertising, a provider may not pay any third person for a referral of a claimant without violating the law. Violation of this statute is cause for discipline and constitutes unprofessional conduct, which could result in regulatory penalties, including refusal, revocation, or suspension of a professional license or right or admission to practice. RCW 48.30A.040.

2. RCW 19.68.010.

RCW 19.68.010 is the anti-rebating law that prohibits referral of patients to other providers whom the referring physician has an ownership in the practice without prior disclosure in writing to the patient.

It shall be unlawful for any person, firm, corporation or association, whether organized as a cooperative, or for profit or nonprofit, to pay, or offer to pay or

allow, directly or indirectly, to any person licensed by the state of Washington to engage in the practice of medicine and surgery, drugless treatment in any form, dentistry, or pharmacy and it shall be unlawful for such person to request, receive or allow, directly or indirectly, a rebate, refund, commission, unearned discount or profit by means of a credit or other valuable consideration in connection with the referral of patients to any person, firm, corporation or association, or in connection with the furnishings of medical, surgical or dental care, diagnosis, treatment or service, on the sale, rental, furnishing or supplying of clinical laboratory supplies or services of any kind, drugs, medication, or medical supplies, or any other goods, services or supplies prescribed for medical diagnosis, care or treatment. Ownership of a financial interest in any firm, corporation or association which furnishes any kind of clinical laboratory or other services prescribed for medical, surgical, or dental diagnosis shall not be prohibited under this section where (1) the referring practitioner affirmatively discloses to the patient in writing, the fact that such practitioner has a financial interest in such firm, corporation, or association; and (2) the referring practitioner provides the patient with a list of effective alternative facilities, informs the patient that he or she has the option to use one of the alternative facilities, and assures the patient that he or she will not be treated differently by the referring practitioner if the patient chooses one of the alternative facilities.

Any person violating the provisions of this section is guilty of a misdemeanor.

3. RCW 74.09.240.

RCW 74.09.240 prohibits self-referrals and kickbacks with medical assistance patients and is the Washington state version of the Stark Federal Act.

O. Whistleblower Lawsuits.

Whistleblower lawsuits are on the rise. They are increasingly brought by competitors and former employees. An individual may blow the whistle for a variety of reasons, including, to send a message or clean up the industry, to make money, to even the playing field as a competitor, for vindication, or as an offensive tactic rather than be faced with personal liability, if the whistleblower was involved in any wrongdoing.

1. Adopting a Uniform Reporting Process.

To avoid corporate exposure to these penalties, corporations should adopt a uniform reporting process to address retaliation complaints.

Upon receipt of a complaint of retaliation, the employer must immediately investigate the complaint. While the investigation may be conducted by in-house counsel, retention of outside counsel is recommended. In-house investigations may be viewed as biased and more difficult to protect under the attorney work-product or attorney-client privilege doctrines.

Further, in-house counsel or in-house investigators may be more easily forced into becoming a witness should the claim be filed with the DOL or in federal court. Since corporations are required to have an audit committee to investigate reports of material violations, formation of an independent outside audit committee charged with the responsibility to investigate retaliation claims is also necessary and well advised.

Company liability for retaliatory conduct may arise when the employee provides information or assists with an investigation. Liability may also arise from retaliatory conduct in response to the employee filing, causing to file, testify, participate in or assist in any proceeding filed.

2. Guidelines to Encourage Employees to Report Within the Company Rather Than to Outside Government Agencies.

1. Train all employees, particularly managers and supervisors about the Sarbanes-Oxley provisions and Civil False Claims Act.

2. Adopt and implement policies to encourage confidential or anonymous reporting and discourage retaliation in response to employee reporting.

3. Make sure the policy is comprehensive and explains:

- (a) what constitutes material violations;
- (b) how and to whom to report (with several alternatives);
- (c) how the report will be investigated; and
- (d) how violations will be addressed.

Confidentiality and non-retaliation provisions are imperative. Assure employees that they will not be subject to retaliation for reporting violations. State the employer's intention to keep reports of violations as confidential as possible, subject to such disclosure as may be required to investigate, remedy the situation or to respond to governmental agency inquiries.

4. Distribute the policy to all employees on a periodic basis and have them sign a receipt, acknowledgment form, or sign-off sheet to document distribution.

5. Post the policy prominently. The prohibition against retaliation should be included in bolder print.

6. Make sure persons, other than employee's supervisor, are designated to receive reports of violations. Having an independent auditing committee for this purpose would be the employer's best practice.

7. Follow up on all violations promptly and aggressively. Employers must treat complaints seriously, investigate the allegations thoroughly with trained investigators, and then take appropriate actions designed to end any violation. The employer's compliance audit committee is the best choice for conducting the investigation.

8. Fully document the investigation and any remedial steps taken.

9. Make sure all employees know that the company has a "zero tolerance" policy regarding violations of securities and related laws. A zero tolerance policy must be enforced by managerial, supervisory and non-supervisory employees.

10. Hold supervisors and employees accountable for any personal inappropriate behavior that is, or could be construed to be harassment or retaliation.

3. Situating the Company to Defend Itself Against Retaliation Complaints in Litigation

1. Employers must have an anti-retaliation policy in their manuals and employee handbooks that they may refer to during litigation.

2. If a report of an alleged violation is received, draft a letter to the alleged actor(s) to acknowledge that the company received a report of alleged violations and will have its outside auditors investigate the allegation. Exercise caution in the wording of the letter to emphasize the Company has received notice of “allegations” and that a neutral and fair investigation will be conducted. The tenor of the letter may support slander or defamation claims. This same letter should be drafted for a report of retaliation.

3. In many harassment situations, employers may transfer the complaining employee or otherwise reassign his or her supervisor who is the subject of a retaliation complaint made by the employee. However, courts are split over whether such a transfer constitutes an adverse employment action. To date, courts in general hold that a transfer alone is not adverse, if the working conditions are generally similar and there is no adverse difference in pay. Caution should be used when considering a transfer.

4. If transferring is not appropriate, ensure that the complaining employee has a new supervisor/manager who is unaware of the complaint. Keep the new supervisor/manager ignorant of the reporting since adverse employment actions cannot constitute retaliation if the actor responsible for the adverse employment action was unaware of the “protected conduct.”

5. Conduct an unbiased investigation of the retaliation complaint. As stated previously, retaliation complaints should be investigated by outside firms.

6. Limit communication regarding the material violations complaints to those with a “need to know.”

7. Consider a moratorium on pending adverse actions if you are aware that a lawful report of an alleged material violation has been made. Postponing a demotion, termination or other adverse action may protect the corporation from a retaliation complaint. Keep in mind, harassment, although undefined, is considered criminal under Sarbanes Oxley.

8. Always maintain a paper trail of management deliberations and actions so that records reflect the consideration and decisions regarding adverse actions occurred prior to the report of alleged material violations.

9. Review all retrievable emails to and from the complainant and his or her supervisor and any other knowledgeable employees to assess the gravity of the alleged complaint.

10. When advising employees that a complaint has been received and an investigation will be undertaken, have each employee sign a statement acknowledging they have been advised that retaliatory conduct will not be tolerated.

1. Document Retention

Employers that do not have a reliable system of documentation may have difficulty defending against retaliation actions. There must be good personnel procedures and documentation of poor performance or conduct, etc.

These examples demonstrate how documentation can save the corporation or in other situations, lead to its downfall. Limiting supervisory personnel’s knowledge of employee

complaints of material violations may obviate the potential for the result shown in this example. An audit committee should coordinate the referral of complaints to outside investigators. Limiting distribution of investigative findings may prevent unnecessary disclosure to non-essential personnel.

In short, employers should begin documenting their relationship with their employees from the hiring process through resignation, reduction-in-force, and/or termination. Disgruntled employees often document their employers' actions in excruciating detail and often at the direction of plaintiffs' counsel. Further, jurors often give more weight to written records made before a lawsuit than sworn testimony. Documenting the employment relationship from its onset enables employers to challenge an employee's version of the facts with a competing written record. Employers who consistently document the positive and negative events in an employee's history can better respond to charges of retaliation. Employers with good documentation habits can better explain why an employee was hired, promoted, disciplined, or discharged. In short, employers who establish the documentation habit at the onset of the employment relationship retain the most flexibility in their personnel decisions.

When a complaint has been received, a memo from an authoritative manager, supervisor or director must be issued to all employees advising that no documents, including any written document, document on their computer, documents on their laptop or home computer that are work related, e-mail, and voice mail can be deleted or destroyed until further notice. Getting the employee signature to acknowledge receipt of the notice will assist in defending against any possible charge of interference with a government investigation.

II. CORPORATE COMPLIANCE IN HEALTHCARE

A. Overview.

As in recent years, the OIG will continue to focus its efforts on investigating fraud, abuse and waste activities in the health care industry. The 2004 Work Plan indicates a significant focus on the pharmaceutical industry. According to the U.S. Department of Health and Human Services, Office of Inspector General Fiscal Year 2004 Work Plan:

OI will investigate individuals, facilities, or entities that bill Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes in an effort to inflate reimbursement amounts, and other false claims submitted to obtain program funds. OI will also investigate business arrangements that violate anti-kickback statutes.

Investigative focus areas include pharmaceutical fraud. Working jointly with such partners as the Drug Enforcement Administration and State and local authorities, OI will continue to identify and investigate illegal schemes to market, obtain, use, and distribute prescription drugs. By investigating these schemes, OI aims to deter the illegal use of prescription drugs, curb the danger associated with street distribution of highly addictive medications, stop the inflating of drug prices common in the pharmaceutical industry, and protect the Medicare and Medicaid programs from making improper payments.¹⁵

Accordingly, organizations must understand the fraud and abuse statutes, recognize activities that may run afoul of these statutes and implement effective compliance programs aimed at mitigating risk and reducing unlawful conduct.

B. Compliance Programs: Prevention is Key

The best way to avoid encountering the adverse consequences of increased enforcement against overpayments, fraud and abuse is to prevent the potentially unlawful conduct in the first place. This means an effective compliance program. The OIG has developed and issued voluntary compliance program guidance directed at the following segments of the health care

¹⁵ U.S. Department of Health and Human Services, Office of Inspector General Fiscal Year 2004 Work Plan – Centers for Medicaid and Medicare Services, at p. 41.

industry: the hospital industry, home health agencies, clinical laboratories, third-party medical billing companies, the durable medical equipment, prosthetics, orthotics and supply industry, Medicare+Choice organizations offering coordinated care plans, hospices, nursing facilities, individual and small group physician practices, and ambulance suppliers.¹⁶

Individual physicians as well as members of the board of directors may face personal liability for violations of fraud and abuse statutes. Teaching hospitals face risks with respect to billing guidelines regarding the teaching of resident physicians. The pharmaceutical industry has also come under closer scrutiny recently and faces unique risks regarding kick-backs and other legal remuneration, discounts, product support services, educational grants, research funding, relationships with formulary committee members, payments to PBMs, formulary placement payments, “switching arrangements,” consulting and advisory payments, and business courtesies and other gratuities. These unique risks to the pharmaceutical industry require the development of a specific compliance program addressed to handle these risks.¹⁷

The OIG believes there are seven essential elements to an effective compliance program for any organization, whether a hospital or clinic, or a pharmaceutical manufacturer. The seven elements are modeled on the seven steps of the Federal Sentencing Guidelines.¹⁸ At a minimum, all compliance programs aimed at reducing health care fraud and abuse should include the following seven elements:

¹⁶ For copies of compliance program guidelines, visit OIG Web Site at <http://oig.hhs.gov/fraud/complianceguidance.html>.

¹⁷ 68 F.R. 23731 (May 5, 2003), Notice Department of Health and Human Services, Office of the Secretary of Health and Human Services, Office of the Inspector General, OIG Compliance Program Guidance for Pharmaceutical Manufacturers.

¹⁸ 63 F.R. 8987 (Feb. 23, 1998) (citing United States Sentencing Commission Guidelines, Guidelines Manual, 8A1.2, Comment (n.3(K)).

1. The development and distribution of written standards of conduct, as well as written policies and procedures that promote the hospital's commitment to compliance (e.g., by including adherence to compliance as an element in evaluating managers and employees) and that address specific areas of potential fraud, such as claims development and submission processes, code naming and financial relationships with physicians and other health care professionals.
2. The designation of a chief compliance officer and other appropriate bodies, for example, a corporate compliance committee charged with the responsibility of operating and monitoring the compliance program and who report directly to the CEO and the governing body;
3. The development and implementation of regular, effective education and training programs for all affected employees;
4. The maintenance of a process, such as a hotline, to receive complaints, and the adoption of procedures to protect the anonymity of complainants and to protect whistle blowers from retaliation;
5. The development of a system to respond to allegations of improper/illegal activities and the enforcement of appropriate disciplinary action against employees who have violated internal compliance policies, applicable statutes, regulations or federal health care program requirements;
6. The use of audits and/or other evaluation techniques to monitor compliance and assist in the reduction of identified problem area;

7. The investigation and remediation of identified systemic problems and the development of policies addressing the non-employment or retention of sanctioned individuals.

C. Compliance Programs for Hospitals.

On February 23, 1998, the OIG issued a publication on compliance program guidance for hospitals.¹⁹ The guidance was provided to assist hospitals in implementing compliance programs to address the prevention, detection and resolution of conduct that does not conform to federal and state law, as well as the hospital's own ethical and business policies.²⁰ Each hospital should tailor its own compliance program to the unique risks of its organization. The OIG has identified the following risk areas that hospitals should be specifically aware of in considering written policies and procedures concerning regulatory exposure. These areas of concern include the following:

1. Billing for items or services not actually rendered;
2. Providing medically unnecessary services;
3. Upcoding – The practice of using a billing code that provides a higher payment rate than the billing code that actually reflects the service furnished to the patient.;
4. “DRG creep”—Like upcoding, “DRG creep” is the practice of billing using a Diagnosis Related Group (DRG) code that provides a higher payment rate than the DRG code that accurately reflects the services furnished to the patient;
5. Outpatient services rendered in connection with inpatient stay;
6. Teaching physician and resident requirements for teaching hospitals;

¹⁹ See 63 F.R. 8987 (Feb. 23, 1998)

²⁰ Id.

7. Duplicate billing;
8. False costs reports;
9. Unbundling—The practice of submitting bills piecemeal or in fragmented fashion to maximize the reimbursement for various tests or procedures that are required to be billed together and therefore at a reduced cost;
10. Billing for discharge in lieu of transfer;
11. Patient's freedom of choice;
12. Credit balances – failure to refund;
13. Hospital incentives that violate the anti-kick-back statute or other similar federal or state statute or regulation;
14. Joint ventures;
15. Financial arrangements between hospitals and hospital-based physicians;
16. Stark physicians self-referral law;
17. Knowing failure to provide covered services or necessary care to members of a health maintenance organization;
18. Patient dumping.²¹

Physicians at teaching hospitals should be aware of the following specific risks:

1. Only services actually provided may be billed;
2. Every physician who provides or supervises the provision of services to a patient should be responsible for the correct documentation of the services that were rendered;

²¹ See 63 F.R. 8987 (Feb. 23, 1998).

3. The appropriate documentation must be placed in the patient record and signed by the physician who provided or supervised the provision of services to the patient;
4. Every physician is responsible for assuring that in cases where that physician provides evaluation and management (E&M) services, a patient's medical record includes appropriate documentation of the applicable key components of the E&M service provided or supervised by the physician (e.g., patient history, physician examination, and medical decision making), as well as documentation to adequately reflect the procedure or portion of the service performed by the physician; and
5. Every physician should document his or her presence during the key portion of any service or procedure for which payment is sought.

Hospitals should have specific policies in place to comply with anti-kickback statutes and the Stark physician self-referral law, in particular:

1. All of the hospital's contracts and arrangements with referral sources comply with all applicable statutes and regulations;
2. The hospital does not submit or cause to be submitted to the Federal health care programs claims for patients who were referred to the hospital pursuant to contracts and financial arrangements that were designed to induce such referrals in violation of the anti-kickback statute, Stark physician self-referral law or similar Federal or State statute or regulation; and
3. The hospital does not enter into financial arrangements with hospital-based physicians that are designed to provide inappropriate remuneration to the hospital in

return for the physician's ability to provide services to Federal health care program beneficiaries at that hospital.

Compliance programs guide the hospital's governing body including boards of directors or trustees, chief executive officer, managers, other employees and physicians and other health care professionals in the efficient management and operation of a hospital. There are many benefits of an effective compliance program, including:

1. Concretely demonstrating to employees and the community at large the hospital's strong commitment to honest and responsible provider and corporate conduct;
2. Providing a more accurate view of employee and contractor behavior relating to fraud and abuse;
3. Identifying and preventing criminal and unethical conduct;
4. Tailoring a compliance program to a hospital's specific needs;
5. Improving the quality of patient care;
6. Creating a centralized source for distributing information on health care statutes regulations and other program directives related to fraud and abuse and related issues;
7. Developing a methodology that encourages employees to report potential problems;
8. Developing procedures that allow the prompt, thorough investigation of alleged misconduct by corporate officers, managers, employees, independent contractors, physicians, other health care professionals and consultants;
9. Initiating immediate and appropriate corrective action;

10. Through early detection and reporting minimize the loss to the government from false claims and thereby reduce the hospital's exposure to civil damages and penalties, criminal sanctions and administrative remedies such as program exclusion.

Implementing an effective compliance program may not entirely eliminate fraud, abuse and waste from the hospital system. However, the compliance program can reduce the risk of unlawful and improper conduct.

D. Pharmaceutical Manufacturer Compliance.

The Department of Health and Human Services (HHS) Office of the Inspector General (OIG) issued a notice in the Federal Register setting forth Compliance Program Guidance for Pharmaceutical Manufacturers.²² An effective compliance program is crucial in preventing fraud and abuse in federal health care programs. The guidance identifies three major potential fraud and abuse risk areas for pharmaceutical manufacturers:

1. Integrity of data furnished by manufacturers;
2. Kickbacks and other illegal remunerations; and
3. Compliance with laws regulating drug samples.

The pharmaceutical industry is faced with heightened investigation into fraud and abuse. There are now dedicated healthcare fraud units in every U.S. Attorney's office and in every Inspector General's office and in most FBI offices across the country. In short, pharmaceutical companies have become a prime target of healthcare fraud prosecution.

²² 68 F.R. 23731 (May 5, 2003).

Manufacturers often provide grants to support continuing medical education and other programs. These grants are very often disbursed to customers and potential customers of the pharmaceutical manufacturer. Giving away money in the form of grants can violate the Anti-Kickback statute, the False Claims Act, the Medicaid rebate program and a host of other statutory schemes.²³

The OIG has identified a number of fairly common industry practices that it considers possible kickbacks, including.

1. Payment of “switch fees” to pharmacists;
2. Practice of paying for “research” studies that are never performed or used;
3. “Any prize, gift or cash payment, coupon or bonus” offered to a physician or supplier in exchange for prescribing a conduct;
4. Cash or other benefits are offered to pharmacists (or others in a position to recommend products) in exchange for performing “marketing” tasks;
5. Grants offered to clinicians for studies that are “of questionable scientific value and require little or no actual scientific pursuit”;
6. Payments made to a patient, provider or supplier to change a prescription from one product to another.

Federal authorities have prosecuted manufacturers under the Anti-Kickback statute for grant-giving practices to the tune of \$161 million (the Caremark settlement). Hoffmann-LaRoche paid \$450,000 to settle allegations regarding research grants that were characterized as kickbacks. More recently, AstraZeneca Pharmaceuticals paid \$355 million in civil and criminal

²³ See generally Paul E. Kalb, MD & I. Scott Bass, Government Investigations in the Pharmaceutical Industry: Off-Label Promotion, Fraud and Abuse, and False Claims, 53 FOOD DRUG L.J. 63 (1998).

penalties to settle allegations under the False Claims Act that it conspired to defraud government-backed health plans by distributing thousands of free samples of its prostate cancer drug Zoladex to physicians while encouraging them to seek federal reimbursement for the medication.²⁴ The Vice President of Sales for the corporation filed the suit under the False Claims *qui tam* provisions. As a result, he will take home an estimated \$47.5 million share of the settlement.

Under the Medicaid rebates system, manufacturers are obligated to rebate to the state Medicaid programs, on a per unit basis, either a fixed discount off the “average manufacturer’s price” or the difference between their average manufacturer’s price and their “best price” for covered outpatient drugs.²⁵ “Best price” is defined to include “cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates.”²⁶ Grants can impact “best price” if they are rebates in disguise. Because of this, manufacturers’ rebate practices are under heightened scrutiny by the law enforcement agencies.

Additionally, recently the HHS replaced the three-year record-keeping requirement and with a ten-year requirement, thereby increasing the government’s ability to investigate potential fraud.

The U.S. Attorney’s Office has filed charges against benefits manager Medco Health Solutions, the biggest pharmacy benefit-management company in the U.S. (a spin-off of the pharmaceutical manufacturer Merck) for violations of anti kickback statutes. The lawsuit stems from the government’s intervention in two whistleblower lawsuits alleging that the company

²⁴ AstraZeneca Pays \$355 Million to Settle False-Claims Case, GUN INDUSTRY LITIGATION REPORTER, Vol. 5, No. 8, pg. 28 (Dec. 26, 2003).

²⁵ 42 U.S.C. § 1396r-8(c)(1)(A)

²⁶ 42 U.S.C. § 1396r-8(c)(1)(C)(ii)

committed fraud, falsified records, made false statements to investigators and induced physicians to switch patients to more expensive prescriptions marketed by then-parent company Merck. In its Amended Complaint, the U.S. Attorney's Office added two former Medco employees as defendants in the lawsuit, a former Medco executive vice president and the former general manager of a Medco mail order pharmacy. The Amended Complaint alleges that the two Medco executives canceled, deleted and destroyed prescription orders to avoid penalties for not satisfying their contractual obligations with Blue Cross Blue Shield.

The high cost of noncompliance is a reality. Violations of the statutory schemes carry criminal penalties and substantial financial penalties. Board members and directors may face personal liability. An even greater penalty is that the FDA may delay a new drug application.

Manufacturers need to take several measures to stay ahead and out of trouble²⁷:

1. Know all statutory and regulatory schemes and be aware of the regulatory implications of all actions;
2. Undertake a formal or informal internal audit or inquiry to determine if their activities are exposing them to liability under any relevant statutory scheme.
3. Develop policies and procedures designed to address potential exposure ;
4. Train and retrain employees, including management to understand the various laws;
5. Adopt a comprehensive compliance program;
6. When an investigation arises, plan and execute a strategy as soon as possible to avoid misleading the public.

²⁷ Paul E. Kalb, MD & I. Scott Bass, Government Investigations in the Pharmaceutical Industry: Off-Label Promotion, Fraud and Abuse, and False Claims, 53 FOOD DRUG L.J. 63, 69 (1998).

Several manufacturers when faced with investigations have executed plans to minimize investor concern and distrust by explaining the fraud and abuse allegations and “coming clean” with any potential wrongdoing. This strategy has been effective for many organizations to enhance trust and confidence after the Enron and WorldCom scandals.

E. Board of Director and Individual Liability

The OIG has published a resource guide for boards of directors aimed at reducing director liability under fraud and abuse statutes. The failure of a corporate director to attempt in good faith to institute a compliance program in some situations may be a breach of a director’s fiduciary obligations.²⁸ Generally, the duty of care of a board involves determining whether the directors acted (1) in “good faith”, (2) with that level of care that an ordinarily prudent person would exercise in like circumstances, and (3) in a manner that they reasonably believe is in the best interest of the corporation. In Washington, directors have a fiduciary responsibility to exercise ordinary care in performing their duties and are required to act reasonably and in good faith.

In Caremark, the court noted,

“[A] director’s obligation includes a duty to attempt in good faith to assure that a corporate information and reporting system, which the Board concludes is adequate, exists, and that failure to do so under some circumstances, may, in theory at least, render a director liable for losses caused by non-compliance with applicable legal standards.”

In Caremark, the court observed that the level of detail that is appropriate for such an information system is a matter of business judgment. Under Caremark, a director’s failure to reasonably oversee the implementation of a compliance program may put the organization at risk

²⁸ See In re: Caremark International, Inc. derivative litigation, 698 A.2d 959 (Ct. Chanc. Del. 1996).

and may, in some extreme circumstances, expose individual directors to personal liability for losses caused by the corporate noncompliance.

The health care industry operates in a heavily regulated environment with multiple risk areas. There are unique challenges for health care organization directors, especially in light of the increased oversight and focus on health care fraud and abuse. Failure to comply with federal and state statutes and regulations can be devastating for a health care organization since federal and state-sponsored health care programs play a significant role in paying for health care. In addition to criminal and civil monetary penalties, health care providers found to have defrauded federal health care programs may be excluded from participation in these programs. The crippling effect of financial penalties and exclusion from federal programs may be the death knell for some organizations. The focus on “corporate responsibility” places additional pressure on health care organization directors to implement and carry out effective corporate compliance programs.

F. Individual Liability: A Look Back By H. Richard Winn, MD.

After a nearly three-year investigation regarding allegations of over billing of Medicare, Medicaid and Tri-Care²⁹ programs at the University of Washington, Dr. H. Richard Winn, a prominent neurosurgeon and Chair of the Department of Neurological Surgery plead guilty to one obstruction of just charge, was forced to resign his position as chair and forfeit his operating privileges. Dr. Winn accepted a plea deal in which he was ordered to serve 1,000 hours of community service and pay a \$4,000 fine and repay \$500,000 to government programs. In addition, Dr. Winn was ordered by the court, “to publicize through a professional medical

²⁹ Military health system sponsored care

journal a declaration regarding the errors in compliance with federal rules and regulations relating to health care benefits programs at the UW Department of Neurology Surgery.”³⁰ In Dr. Winn’s plea agreement, the government stipulated that billing claims submitted by Winn were not intentional but “the product of mistake and confusion.”³¹ Despite the lack of intent, the billing scandal may result in the imposition of millions of dollars paid in civil monetary penalties.

1. Where Did the UW Go Wrong? A Product of Confusion.

The government’s investigation centered around five areas in the UW Neurosurgery Department: (1) eligibility of chief residents to submit claims for professional services; (2) retrospective documentation by chief residents; (3) radio surgery fees; (4) bedside procedures; and (5) operating room presence. Dr. Winn addressed each of these five areas of “confusion” in his article.

In 1996 the HCFA regulations changed and required an attending physician to be physically present (“shoulder-to-shoulder, elbow-to-elbow”) during bedside procedures.³² Prior to the 1996 changes in the HCFA guidelines, there was no requirement for faculty to be physically present during these procedures.³³ In 1996, there was no office or University of Washington Physicians (“UWP”)³⁴ officer responsible for compliance and oversight. According to Winn, such an individual could have prevented the generation of fees for procedures

³⁰ See H. Richard Winn, M.D., Errors in compliance with federal rules and regulations relating to healthcare benefit programs: the University of Washington Department of Neurological Surgery experience, J. NEUROSURG 100:47-55, Jan. 2004.

³¹ Carol Smith, Eminent Surgeon Sentenced in Billing Scandal Winn Receives Fine. Community Service But No Jail Time For Obstruction of Justice During Inquiry, THE SEATTLE POST-INTELLIGENCER, Oct. 29, 2002.

³² Winn, J. NEUROSURG 100, supra note 30, at p. 52.

³³ Id.

³⁴ The UWP is a non-profit entity that operates as the billing arm for all clinical faculty (physicians, nurse practitioners and psychologists) at the University of Washington, including University of Washington Medical Center, Harborview Medical Center and Fred Hutchinson Cancer Research Center.

performed without the presence of an attending.³⁵ In 2000, UWP created the position of UWP director of regulatory compliance and inappropriate billing was identified and the Neurosurgery department ceased billing for bedside procedures where faculty attendings were not present.³⁶

Additionally, the government contended in the investigation that there were many surgical fees submitted for operative procedures performed in the absence of an attending surgeon.³⁷ The government's allegations were based mainly on the nursing operating room record, which upon review, was determined to be inconsistent and an unreliable indicator of an OR presence.³⁸ Dr. Winn credits most of the confusion to a lack of oversight by UWP, coupled with a lack of communication between UWP and departmental administration.

Dr. Winn offered the following advise to other Medicare billers: "trust but verify." It is ultimately the individual provider who signs the agreement, which holds them responsible for errors or cheating.

2. Considerations for Organizing an Effective Compliance Program in the Academic Medical Center– Dr. Winn's Perspective.

In his article Dr. Winn makes the following recommendations for academic medical centers:

that medical schools have a structured orientation process for all new chairs of clinical departments, which should rigorously cover regulations governing the CMS [Centers for Medicare and Medicaid Services] and residency programs as well as research funding (a potential area of future federal focus). All new residency program directors should be familiar with and review on a regular basis specialty board residency guidelines and requirements.³⁹

³⁵ Id.

³⁶ Id.

³⁷ Id. at 53.

³⁸ Id.

³⁹ Id. at 50.

Dr. Winn noted a faculty practice plan must notify faculty members that individuals will be held responsible for their own billing errors and those acting on their behalf. This is a strong inducement for faculty scrutiny. In addition, Dr. Winn acknowledges the presence of an active compliance program is essential in today's environment and must be "carefully considered." Specifically, Dr. Winn notes a compliance program may be hindered by being too centrally directed. A compliance program should not be focused simply on evaluating "numbers" as that is too removed from the "shop floor." Therefore, the compliance program should be tailored to address any potential specialty billing practices. Dr. Winn also notes that a peripheral compliance effort on a departmental level may be compromised by friendships and collegial interactions. Financing is also crucial. Organizations may have a tendency to skimp on financial support and centralized planners may resort to adopting an attitude of "don't ask, don't tell." Faculty at the departmental level may lack the enthusiasm to support the bureaucratic effort of a compliance program in the era of diminishing reimbursements and lower salaries. Therefore, faculty, staff and department administration need to provide the incentive – negative and positive – to cooperate and comply with a compliance program.⁴⁰

The consequences of non-compliance are harsh. In the case of the UW, there were two faculty members faced with personal liability resulting from the charges. As Dr. Winn notes, "[F]aculty members must acquire a comprehensive understanding of health care regulations or face personal peril."⁴¹ Dr. Winn faced civil monetary penalties, a criminal plea bargain and was forced to resign his faculty position. The head of the Nephrology Section of the Department of Medicine plead guilty to a single felony count of mail fraud in submitting a \$124 bill for a

⁴⁰ Id. at 52-53.

⁴¹ Id. at 55.

dialysis treatment at which he was not present. The UW regents recently rejected a proposed \$35 million settlement, which would have been the nation's highest over billing penalty involving a teaching hospital. The UW will likely pay out in the range of \$20 to \$30 million to settle the Medicare and Medicaid over billing charges.

G. Self-Disclosure,

Even with a compliance program in place, organizations that run into trouble with fraud and abuse statutes should carefully evaluate the option of self-disclosure. Under the False Claims Act, 31 U.S.C. 3729-3733, a person who has violated the act, but who voluntarily discloses the violation to the government, in certain circumstances will be subject to not less than double, as opposed to treble, damages.⁴² Some cases settled by the OIG result from the self-disclosure to the OIG. The OIG takes the self disclosure and the provider's level of cooperation into account in determining appropriate settlement terms. OIG will often require less money to be paid in settlement for conduct that has been self disclosed. Self-disclosure cases are more likely to settle without requiring integrity provisions or to require more limited integrity provisions.⁴³ The OIG has published a self-disclosure protocol, which provides health care providers specific steps, including a detailed audit methodology that may be undertaken if they wish to work openly and cooperatively with OIG to efficiently quantify a particular problem and ultimately promote a higher level of ethical and lawful conduct within the health care industry.

⁴² 31 U.S.C. § 3729(A)

⁴³ See the Inspector General's November 20, 2001 Open Letter and the OIG's Assessment of CIA Modifications for Self Disclosures) located at OIG.hhs.gov/fraud/enforcement/administrative/cmp.

However, a provider deciding whether to self disclose should consider the risks associated with self disclosure. It may not be appropriate in every situation. The OIG's self-disclosure protocol is voluntary and risks and benefits of disclosure should be weighed.⁴⁴

Risks

1. No guarantee of immunity or reduced penalties exists.
2. Cost of use of internal resources and retention of outside resources to conduct the investigation can be substantial.
3. Employees and other personnel feel under siege, morale sinks, lose good people.
4. Waiver of applicable privileges may be demanded as a condition of being considered to have acted in good faith.

Benefits

1. Demonstration of good faith might improve penalty result, especially when compared to situation if criminal authorities discover and prosecute.
2. After negotiating the investigation protocol, the provider may conduct the investigation. The OIG reserves the right, however, to reject the result.
3. Employees and other personnel are proud that their organization is "doing the right thing."

Another consideration in self-disclosure is the risk of a potential whistleblower who may initiate a *qui tam* lawsuit. It is in the organization's best interests to identify any potential wrongdoing and immediately undertake an internal audit or investigation into the alleged conduct.

⁴⁴ R. Kenneth Gordon, Feature: Healthlaw: The OIG Steps Up Fraud Enforcement: What That Means For the Health Care Industry, 65 TEX. B. J. 837 (Oct. 2002) (citing 63 F.R. 58399, Department of Health and Human Services, Office of Inspector General, Publication of the OIG's Provider Self-Disclosure Protocol (Oct. 30, 1998)).

H. Corporate Integrity Agreements.

Corporate Integrity Agreements (CIAs) are used by the OIG to settle overpayment obligations involving the OIG and to resolve civil enforcement issues tied to criminal prosecutions. As part of its settlements of Federal health care program investigations, the OIG imposes compliance obligations on health care providers. These provider compliance obligations often take the form of a CIA, which is executed between the provider and the OIG. Under a CIA, a provider consents to certain obligations as part of a civil settlement and/or in exchange for the OIG's agreement not to exclude that health care provider from participating in Medicare, Medicaid and other Federal health care programs. Generally, providers who settle these cases do not admit they were liable for the conduct allegedly committed.

A typical CIA is for a term of five years and requires the provider to implement a variety of compliance measures. The OIG generally requires the submission of periodic reports concerning the provider's compliance efforts and reserves the right to impose sanctions for a material breach of the CIA. A provider is often able to limit the scope and reduce the cost of a CIA depending on a variety of factors, including the severity of the alleged misconduct, whether the conduct was self-disclosed, and whether the provider had implemented a compliance program. In some instances, a provider may avoid the imposition of a CIA altogether through self-disclosure and pre-existing compliance efforts.

III. DISCUSSION ON REFORM AND THE FUTURE

The benefits of enhanced corporate governance and compliance are more than mitigating risk and reducing fraud and abuse. Compliance programs foster a sense of investor and public trust. An effective compliance program, which outlines policies and procedures for recognizing

and reducing risk of health care fraud and abuse increases trust and confidence among employees, staff, and directors (all levels of the organization). As a result, this can reduce the likelihood of a qui tam lawsuit because employees are more likely to report within when they know policies are in place to protect them against retaliation.

Critics claim the False Claims Act is not only overbroad and over-reaching but is not intended to address health care fraud and abuse, thereby resulting in inconsistent enforcement. Jurisdictions apply the law differently. In the case of the Medco Health Solutions lawsuit, Medco defends the False Claims Act charges on the basis that the case is little more than “distorted allegation” woven into “a long-winded attempt to concoct a cause of action completely untethered to the False Claims Act.” Medco feels that the government has unfairly thrown all the FCA language and rubric into lengthy complaints hoping that something will withstand dismissal.

An additional criticism of the FCA’s application to health care fraud is whether the government should prosecute cases in which there is no evidence of economic damage to the government. The government takes the position that despite little or no economic harm, in certain cases, corrective action is needed to maintain the integrity of the process. In cases in which no economic harm is demonstrated, the government is paying millions to prosecute actions, which are ultimately borne by the taxpayers.

Finally, the number of statutes regulating the health care industry is startling. If they don’t get you one way, they will get you another. The duplicity and overlap of multiple penalties for the same conduct may be excessive and a hindrance to compliance. Bottom-line, enforcement efforts are on the rise, and organizations must be aware of the risks.

IV. RESOURCES

Office of Inspector General--U.S. Department of Health and Human Services

www.hhs.gov/oig

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

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

For advisory opinions regarding Medicare and Medicaid programs, go to the Centers for Medicare and Medicaid website at <http://cms.hhs.gov/>

A complete list of contact information (address, phone number, email address) for Medicare Part A Fiscal Intermediaries, Medicare Part B Carriers, Regional Home Health

Intermediaries, and Durable Medical Equipment Regional Carriers can be found on the HCFA web site at www.hcfa.gov/medicare/incardir.htm.

Contact information (address, phone number, email address) for each State Medicaid carrier can be found on the HCFA web site at www.hcfa.gov/medicaid/mcontact.htm. In addition to a list of Medicaid carriers, the web site includes contact information for each State survey agency and the HCFA Regional Offices. Contact information for each State Medicaid Fraud Control Unit can be found on the OIG web site at www.hhs.gov/oig/oi/mfcu/index.htm.

Health Care Financing Administration www.hcfa.gov