

**FRAUD AND ABUSE LEGISLATION:
AN UPDATE OF THE CURRENT CASE LAW**

By

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I. INTRODUCTION

The title of this National Business Institute seminar is, *Getting What's Owed: Health Care Reimbursement in Ohio.* As the name implies, its purpose is to allow health care providers in Ohio to understand how to be *properly* reimbursed for the services you provide. I have emphasized the word properly because it is my job to tell you how to avoid getting caught up in the fraud and abuse web and to stay out of trouble with the enforcement authorities.

To put this in perspective, one only has to look at the recoveries from the health care industry by the federal government over the past several years. Since 1986, the year Congress changed to False Claims Act (FCA) to make it easier for whistleblowers to file lawsuits under the act on behalf of the government, over \$13,500,000,000 has been recovered by the federal government. The whistleblower's share of these recoveries is \$1,422,000,000.¹ Small wonder that most cases under the Act are brought by disgruntled employees. I will discuss the FCA and its implications to health care providers below. However, it is important to recognize that the FCA is the most frequently used tool by federal prosecutors to enforce health care fraud and abuse laws. I will also discuss how violation of other laws and regulations, such as the Anti-Kickback Statute and Stark, provides the basis for a false claim actionable under the Act.

¹Source: The False Claims Act Legal Center, *False Claims Act and Qui Tam Statistics*, September 30, 2004.

II. FEDERAL FALSE CLAIMS ACT²

What is the False Claims Act?

- ! A federal statute that prohibits, among other things, anyone from presenting a false or fraudulent claim for payment to the Federal Government, or causing the use of a false record to get a claim paid by the Federal Government.
- ! In the health care context, this would include billing for work not performed, upcoding, billing for unnecessary services, and even billing for services that were obtained in violation of other laws and/or regulations (such as the Anti-Kickback Statute).

History of the False Claims Act

- ! The original Act was passed in 1863, under President Lincoln, to combat fraud by war profiteers.
- ! The Act was amended in 1986 to encourage its use as a weapon against fraud. The number of cases filed since the 1986 amendments has risen from 33 in 1987 to 278 in 1995.

How does the False Claims Act Work?

- ! The False Claims Act provides a financial incentive for people with knowledge of false claims against the Federal Government to come forward. It does so by awarding a successful relator (the plaintiff in a False Claims Act case) with between 15-30% of any recovery from a defendant.
- ! The relator files a False Claims Act suit (also called a Qui tam@ suit) on behalf of the United States. It is filed under seal (not a public document), along with a disclosure statement providing evidence to the government.
- ! While under seal, the government investigates the allegations, and decides whether to intervene. During this period, the defendant may not even be aware a False Claims Act case has been filed. If the government intervenes, the government is the primary prosecutor (although the relator

² 31 U.S.C. §§3729-32, as amended, Pub. L. 99-562, 100 Stat. 3153 (1986).

still has input), and the relator receives 15-25% of any recovery. If the government does not intervene, the relator can still go forward with the suit and, if successful, receives 25-30% of any recovery.

How Is a False Claims Act Violation Proved?

- ! The relator must show that the defendant was responsible for a false claim to the Federal Government. The evidence of this is initially presented in a disclosure statement, submitted to the Government when the complaint is filed. This disclosure statement sets forth all of the evidence the relator possesses regarding the false claim, and generally points the Government to additional persons or documents that would substantiate the allegations.
- ! The evidence provided needs to be as detailed as possible. It is not sufficient to base a complaint on rumors of wrongdoing; there should be specific allegations showing the time, date, place and content of any false claim. It is also helpful to have documentation supporting the allegations.
- ! The false claim must be shown by the civil standard - preponderance of the evidence (more likely than not); it does not have to be shown by the criminal standard - beyond a reasonable doubt. Specific intent to defraud need not be shown. *Knowingly* is defined to include acting with *deliberate ignorance* or *reckless disregard* of the truth or falsity of the information.
- ! These burdens of proof were clarified and relaxed by the 1986 amendments, in part to prevent the ostrich or *head in the sand* defense. For example, a physician signing off on a HCFA 1500 form would find it difficult to defend a False Claims Act violation by claiming that he knew nothing of the billing practice and left it all to his staff.

What Damages Are Recoverable?

- ! A defendant found liable is responsible for treble damages, costs, attorneys' fees, and penalties. The penalties are a mandatory \$5000 - \$10,000 per false claim. For example, if a physician submits five HCFA 1500 forms to Medicare for five separate physicals that were never performed, and that physician receives \$50 for each physical, the damages could be as follows:

- Compensatory damages of \$250 (for the five physicals), trebled to \$750;
- Reasonable costs of prosecuting the suit;
- Reasonable attorneys' fees for the relator; and
- Statutory penalties between \$25,000 and \$50,000.

Who Can Bring a False Claims Act Case?

- ! Anyone with knowledge of the illegal conduct. This is often a current or former employee of a defendant. However, if the relator planned and initiated the false claims violation, the award to the relator may be reduced; if the relator is criminally convicted for his or her role, they must be dismissed from the suit.

Are There Time Limits for a False Claims Act Case?

- ! suit must be brought within six years from the date of the false claim, or within three years after the Government knows or should have known of the false claim, but in no event later than ten years after the false claim.

What Limitations Are There on False Claims Act Suits?

- ! If the allegations in the False Claims Act suit were already publicly disclosed, the relator has to be the original source of the allegations that brought the information to the Government before filing an action.
- ! No False Claims Act suit can be brought where the allegations are already the subject of a civil suit or administrative civil monetary penalty proceeding where the Government is a party.
- ! Government knowledge or waiver of the false claim does not provide an absolute defense, but may make it difficult to prove a False Claims Act case.

What Are the Risks of Filing Suit?

- ! Once a decision to intervene is made, the case is unsealed, and the identity of the relator is revealed. This may lead to retaliation by a defendant. However, a section of the False Claims Act provides strong protections for

whistleblowers, and may be successfully invoked whether or not the underlying False Claims Act violation is ever proven.

- ! If the defendant prevails in the suit, and the court finds the suit was clearly frivolous, vexatious or brought for harassment, then the court may find the relator liable for the defendant's expenses and fees.

Is the False Claims Act Being Used in the Health Care Field?

- ! Not only has the number of False Claims Act cases risen dramatically since 1986, but also there is a distinct trend toward health care fraud cases. In 1994, only 18% of the cases involved health care fraud; of the \$2.1 billion collected in 2003, \$1.7 billion, almost 81 percent, involved health care fraud.³
- ! Of the top five False Claims Act recoveries in 1996, four were in the health care field (the recovery against Laboratory Corporation of America was the largest - \$182 million for medically unnecessary tests submitted to Medicare, Medicaid and CHAMPUS). In 2003, there was a recovery from HCA, Inc. for \$641 million (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. Other recoveries included \$382 million from Abbott Laboratories and its Ross Products Division and \$280 million from AstraZeneca Pharmaceuticals, LP. In the 5-year period from 1999 to 2003, the Federal government spent \$409.6 million to recover \$5.21 billion in health-care fraud related settlements and judgments.⁴
- ! Violations of the anti-kickback and/or self-referral laws can also result in False Claims Act liability. The Sixth Circuit stated: A. . . it is clear that the False Claims Act was intended to cover not only those situations in which the claims themselves are false but also those situations in which a claimant engages in fraudulent conduct with the purpose of inducing payment by the government . . .⁵ Because the defendant had not

³United States Department of Justice Press Release, AJustice Dept. Civil Fraud Recoveries Total \$2.1 Billion for FY 2003; False Claims Act Recoveries Exceed \$12 Billion since 1986, @ Nov. 10, 2003. (There was no press release on the subject in 2004.)

⁴Jack A. Meyer, *Fighting Medicare Fraud: More Bang for the Federal Buck*, a report prepared for Taxpayers Against Fraud Education Fund, April 2005, p. 3.

⁵*United States ex rel. Augustine v. Century Health Services, Inc.*, 289 F.3d 409, 414-15 (6th

complied with these Medicare program guidelines, and nonetheless executed the cost report certifications, it had violated the FCA. Moreover, the district court also concluded that when the defendant executed the *explicit* cost report certifications, it was also *implicitly* certifying that it would continue to comply with the applicable regulations or file an amended cost report reflecting its non-compliance.⁶

In 2003, the Federal District Court for the Northern District of Illinois held that . . . an Anti-Kickback Statute violation is material to the treatment of Medicare reimbursement claims. Therefore, . . . the alleged violation of the Anti-Kickback Statute (AKS) was material to the government's treatment of the Medicare claims and . . . the submissions violated the FCA.⁷

As recently as September 9, 2005, the Eleventh Circuit held that : A . . . compliance with the [Anti-Kickback] Statute is necessary for reimbursement under the Medicare program; and the [Defendants] submitted claims for reimbursement knowing that they were ineligible for the payments demanded in those claims.⁸

With this last comment in mind, let us review the self-referral laws, the so called Stark Law and the Anti-Kickback Statute.

Cir. 2002).

⁶*United States ex rel. Augustine v. Century Health Services, Inc.*, 136 F. Supp.2d 876, 886 (M.D. Tenn. 2000)

⁷*United States ex rel. Bidani v. Lewis*, No. 97 C 6502 (N.D. Ill. Mar. 4, 2003)

⁸*United States ex rel. McNutt v. Haleyville Medical Supplies, Inc.*, No. 01-03156-CV-AR-J (11th Cir. Sept. 5, 2005)

III. STARK I AND STARK II

One of the great misconceptions in the health care industry is that the Anti-Kickback Statute and Stark are the same. They are not! While they are intertwined and refer to each other regarding specific issues, the two laws address different concepts. The Anti-Kickback law prohibits payment for referrals; Stark prohibits referrals to an owned facility or a facility with which the physician has a compensation arrangement. As stated by the OIG:

Compliance with a Stark law exception does not immunize an arrangement under the anti-kickback statute. Rather, the Stark law sets a minimum standard for arrangements between physicians and hospitals. Even if a hospital-physician relationship qualifies for a Stark law exception, it should still be reviewed for compliance with the anti-kickback statute.⁹

The Ethics in Patient Referral Act of 1989, enacted on December 19, 1989 (AStark I@), as amended by the Omnibus Budget and Reconciliation Act of 1993 (AStark II@) and ultimately incorporated into Sections 1877 and 1903(s) of the Social Security Act (ASSA@) (hereinafter, Stark I and Stark II will be referred to collectively as the AStark Law@).

Stark I prohibited referrals to clinical laboratories in which the physician has a financial interest. The Stark Law, as amended, prohibits physicians from referring to an entity in which the physician has a financial relationship any Medicare and Medicaid patients. This includes referrals to a clinical laboratory or for designated health services.¹⁰

Prohibited financial relationships include ownership and investment interests and compensation arrangements. Ownership or investment interests may be through equity, debt, or other means, and include indirect ownership interests through other entities.

⁹70 *Fed. Reg.* 4863 (Jan 31, 2005)

¹⁰In addition to clinical laboratory services, there are ten designated health services, including: (1) physical therapy services, (2) occupational therapy services, (3) certain radiology services, (4) radiation therapy services and supplies, (5) durable medical equipment and supplies, (6) parenteral and enteral nutrients, equipment, and supplies, (7) prosthetics, orthotics, and prosthetic devices and supplies, (8) home health services, (9) outpatient prescription drugs and (10) inpatient and outpatient hospital services.

Compensation arrangements include virtually any form of remuneration. A physician is defined to include immediate family members of the physician.

Violation of The Stark Law does not depend on a showing of any improper intent. In the preamble to The Stark Law implementing regulations (which implement the original Referral Act, prohibiting referrals to clinical laboratories), the government rejected any good faith or actual knowledge standard for compliance. The Department of Health and Human Services said providers have "the responsibility . . . to take whatever steps are necessary to ensure that they do not violate Federal law."¹¹

The remedy is denial of Medicare or Medicaid payment. However, in three situations, civil monetary penalties and exclusions from the Medicare and Medicaid programs may be imposed:

1. where a person knows or should know that an improper claim has been made or where a refund has not been made (penalty of up to \$15,000 for each prohibited service provided);
2. where a person knows or should know that the purpose of the arrangement is to circumvent The Stark Law (penalties of up to \$100,000 for each scheme); and
3. for false reporting under The Stark Law (penalty not to exceed \$10,000 per day).

Phase I of the regulations implementing the Stark Law was issued on January 4, 2001¹² and Phase II on March 26, 2004.¹³ The regulations provide several exceptions to the reach of the Stark Law.

Exceptions

There are several exceptions to the prohibition against referrals. While it is beyond the scope of this handout to provide an in-depth discussion of these exceptions, it is pertinent to let the reader know what they are and to briefly discuss some of the more important ones.

¹¹60 *Fed. Reg.* 41,924 (Aug. 14, 1995).

¹²66 *Fed. Reg.* 856 (Jan. 4, 2001).

¹³69 *Fed. Reg.* 16054 (Mar. 26, 2004).

While there is not a specific exception for a Agroup practice,@ and simply meeting the requirements of a Agroup practice@ does not provide protection, the first step in qualifying under a number of exceptions, including the physician services exception and the in-office ancillary services exception, is to qualify under the statutory definition of a group practice.

In the Phase I regulations, a group practice is defined as a group of two or more physicians, legally organized as single entity, in which at least 75 percent of the full range of services is substantially provided by members of the group, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment and personnel. This is referred to as the full range of service test. Services are billed under a billing number assigned to the group and amounts so received are treated as receipts of the group, the substantially all test. The overhead expenses and the income of the practice are distributed in accordance with methods previously determined, the unified business test. No physician who is a member of the group directly or indirectly receives compensation based on the volume or value of referrals by the physician, except for pre-determined profit distributions and personal productivity bonuses.¹⁴

In the Phase II regulations, this definition was slightly modified. The single legal entity test and primary purpose test are modified to specify that the inquiry is whether the group is functioning as a physician group practice, not some other entity such as a hospital. That is not to say that a hospital cannot acquire a physician group practice that qualifies, however. In addition, the two or more physicians that are members of the group must be direct or indirect owners, employees, locum tenens physicians or on-call physicians. They cannot be independent contractors.¹⁵

Under the Phase I unified business test, groups were required to centralize utilization review. Since many group practices do not perform utilization review, this requirement has been eliminated in Phase II.¹⁶

The incident to test was also clarified to make clear that a physician in the group can be paid a profit share based on services he or she directly performs or that are provided incident to his or her services. The commentary cautions, however, that if a group practice uses the *bona fide* employment, personal services arrangement or fair

¹⁴ 66 *Fed. Reg.* 956-957 (2001).

¹⁵ 69 *Fed. Reg.* 16077 (2004).

¹⁶ 69 *Fed. Reg.* 16080 (2004).

market value exceptions to protect referrals from independent contractors, the compensation requirements under those exceptions must be satisfied.¹⁷

The Phase I regulations specified several exception to the referral prohibition related to both ownership/investment and compensation and to compensation arrangements by themselves. The physician services exception applies to services furnished personally by another physician who is a member of the referring physician=s group practice or under the supervision of another physician who is a member of the referring physician=s group practice or is a physician in the same group practice. However, while this exception includes incident to services, it is only those incident to services that are physician services. In other words, it does not apply to incident to services such as diagnostic tests and physical therapy.¹⁸

There is also an exception for in-office ancillary services. These are services, including certain DME items (canes, crutches, walkers and folding manual wheelchairs, and blood glucose monitors), but excluding others, that are (1) furnished personally by the referring physician, a member of his or her group practice, or an individual under the supervision of the referring physician or a member of his or her group practice, (2) furnished in the same building or a centralized building used by the group, and (3) billed by the physician, the group, an entity wholly owned by the group, or an independent billing company acting as agent for the group. There is also a special rule for home care physicians.¹⁹

There are also exception applying to managed care organizations, clinical laboratory services furnished in an ambulatory surgical center, academic medical centers, implants in an ambulatory surgical center, dialysis-related drugs in an end stage renal disease facility, preventable screening tests, and eyeglasses and contact lenses for cataract surgery.²⁰

With regard to compensation arrangements, there is an exception for non-monetary compensation up to \$300, fair market value compensation (basically following the same requirements as the anti-kickback statute), medical staff incidental benefits, risk sharing arrangements, compliance training, and indirect compensation.²¹

¹⁷69 *Fed. Reg.* 16080 (2004).

¹⁸66 *Fed. Reg.* 959 (2001).

¹⁹66 *Fed. Reg.* 959-60 (2001).

²⁰66 *Fed. Reg.* 960-61 (2001).

²¹66 *Fed. Reg.* 961-62 (2001).

There is a general exception in the law regarding ownership in publicly traded securities. Phase II modifies this to reflect that stock options and convertible securities will be treated as compensation, not ownership until they are exercised.²²

Recent Caselaw

Aside from several cases alleging violation of the Anti-Kickback Statute and Stark Law as the basis for a False Claims Act suit, I can find no recent cases, other than those identified above under the Anti-Kickback Statute discussion, regarding violation of Stark.

²²69 *Fed. Reg.* 16062-63 (2004).

Ohio Law

The Ohio prohibition on physician referrals to owned facilities is similar to the Referrals Act. However, while it is applicable to all payors, it is limited to referrals to clinical laboratories, home health and outpatient prescription drugs. In addition, there are exceptions that generally follow the exception in the federal law.²³

We have discussed the Stark Law, now let us turn our attention to the Anti-Kickback Statute.

²³ORC § 4731.65-4731.67.

IV. FEDERAL ANTI-KICKBACK STATUTE

One of the most familiar Medicare/Medicaid fraud and abuse laws is Section 1128B(b) of the Social Security Act (42 U.S.C. ' 1320a-7b(b)), often referred to as the "Anti-Kickback Statute" (the AStatute@). The Statute prohibits the offer or payment, as well as the solicitation or receipt, of "any remuneration (including any kickbacks, bribe, or rebate)" in exchange for referrals. The prohibited activity is a two way street, with both the payer and the receiver equally culpable.

What constitutes "any remuneration," however, is a gray area. While the statute provides that remuneration includes "any kickback, bribe or rebate," it does not define these terms. Further, there is a prohibition against remuneration "directly or indirectly, overtly or covertly, in cash or in kind." Clearly, direct cash payments in exchange for referrals violate the statute. What is less clear, however, is what constitutes "indirect payments."

The intent of the Statute is to eliminate payment for referrals of Medicare/Medicaid patients or business that is paid for by those programs. Any payment, including profit distributions, made to a physician or other healthcare provider by an activity to which he, she or it makes referrals of patients or goods or services is suspect. While the statute is primarily aimed at prohibiting payment to physicians for referrals, it is not limited as such and other providers are not exempt.

There are four specific exceptions to the broad sweep of the general prohibition against remuneration: (1) a discount or price reduction to the provider that is properly disclosed and appropriately reflected in costs claimed or charges made by the provider; (2) payments by an employer to a bona fide employee for employment in the provision of covered items or services; (3) group purchase arrangements established by written contract with full disclosure; and (4) specified limited payment practices, the so-called "safe harbors," under the regulations required by the Medicare and Medicaid Patient and Program Protection Act of 1987²⁴ ("the 1987 Act").

Because the anti-kickback statute is extremely broad in its language, its scope is established by judicial interpretation. To date, the courts have interpreted the statute in an expansive manner. If remuneration flows from one party to another and if referrals (or the opportunity to provide goods and services) flow back, the potential for criminal prosecution exists, regardless of the presence of good business reasons for the venture. Thus, even in the case of what those unfamiliar with the statute might consider normal business arrangements, the shadow of criminal sanction remains.

²⁴P.L. 100-93, 101 Stat. 680 (1987)

Judicial Interpretation:

The leading case applying the anti-kickback statute is *United States v. Greber*,²⁵ dealing with payments between a medical diagnostic company that provided Holter monitor services and physicians. The company billed Medicare for the monitoring services it performed and forwarded 40 percent of those payments (up to \$65 per patient) to the referring physician. The defendant, Dr. Greber, asserted that these payments to referring physicians were "interpretation fees" paid for the initial consultation and for explaining the test results to the patients.²⁶ He argued that compensation for services actually performed did not violate the anti-kickback statute absent a showing that the only purpose of the fee was improperly to induce future services. The court found that the statute prohibited any financial incentives to physicians that might induce unneeded services: "**If one purpose of the payment is to induce future referrals**, the Medicare statute has been violated."²⁷

Under this broad reading of the statute, any payments from a provider to a referral source could violate federal law even if the payments were primarily intended to compensate the referral source for goods and services actually provided. In 1989, this broad interpretation was adopted in the *Kats*²⁸ and *Bay State*²⁹ cases. *Kats* involved an agreement between a community medical clinic and a diagnostic laboratory to share Medicare payments received for laboratory services provided to patients referred by the clinic to the laboratory. Citing *Greber*, the federal appeals court held that the anti-kickback statute was violated if one of the purposes of the payment was to induce future referrals, even for professional services. Conviction is proper unless the payments involved were "wholly and not incidentally attributable to the delivery of goods and services."

In *Bay State*, an executive of a city-owned hospital was charged with receiving illegal remuneration in the form of two automobiles and cash he was paid for services rendered as a consultant to an ambulance company. The government contended he received the cars and money to influence the hospital to award a contract to the ambulance company. Defendants contended that "the government had to show the payments . . . were not as compensation for services performed . . . or were of

²⁵ 760 F.2d 68 (3d Cir. 1985), *cert. denied* 474 U.S. 988 (1985).

²⁶ *Id.* at 70.

²⁷ *Id.* at 69.

²⁸ *U.S. v. Kats*, 871 F.2d 105 (9th Cir., 1989).

²⁹ *United States v. Bay State Ambulance and Hospital Rental Service, Inc.*, 874 F.2d 20 (1st Cir., 1989).

substantially more value than the services performed or to be performed . . . "³⁰ The court found the defendants guilty, stating:

. . . The gravamen of Medicare Fraud is inducement. Giving a person an opportunity to earn money may well be an inducement to that person to channel potential Medicare payments toward a particular recipient . . .

. . . *The statute is aimed at the inducement factor.*

The text refers to "any remuneration." That includes not only sums for which no actual service was performed but also those amounts for which some professional time was expended . . . *That a particular payment was a remuneration (which implies that a service was rendered) rather than a kickback, does not foreclose the possibility that a violation nevertheless could exist.*³¹

The First Circuit Court adopted the more expansive reading of the statute in *Greber*, "stating that the issue of the sole versus primary reason for payments is irrelevant since any amount of inducement is illegal."³²

The Medicare and Medicaid Patient and Program Protection Act of 1987:

Given the direction of judicial interpretation, the Medicare and Medicaid Patient and Program Protection Act of 1987 ("the Act") may be viewed as an effort to respond to the concerns of health care providers that many relatively innocuous, or even beneficial, commercial arrangements are technically within the scope of the statute and hence maybe subject to criminal prosecution. The Act modifies criminal provisions by requiring the promulgation of regulations specifying those payment practices that will not be subject to criminal prosecution and that will not provide a basis for exclusion from the Medicare or state health care programs.³³ The Secretary of HHS, in consultation with the Attorney General, is authorized to develop these regulations. Because the definitions of fraud and abuse in the Medicare/Medicaid statute have changed over time, the Act and its regulations attempt to clarify those practices exempt from consideration as fraud and abuse, that is, safe harbors.

³⁰ 871 F.2d.

³¹ *Id.* at 29-30.

³² *Id.* at 30.

³³ P.L. 100-93 ' 14, 101 Stat. 680, 697-98 (1987).

Safe Harbor Regulations

On July 29, 1991, HHS issued the first final safe harbor regulations.³⁴ On November 5, 1992, three additional safe harbors were published that protect some managed care plans.³⁵ These were updated in 1996.³⁶ On November 19, 1999, eight new safe harbors were published that provide significant benefits to medically underserved areas.³⁷ They protect a variety of arrangements, including physician recruitment, joint ventures, hospital acquisitions of physician practices, and payment of malpractice insurance premiums for obstetrical practices. In December of 2001, a safe harbor for ambulance replenishing was published.³⁸ In September 2002, a rule for waiver of Medicare Select beneficiary coinsurance and deductible amounts was proposed.³⁹ Finally, in July 2005, a safe harbor for federally qualified health centers was proposed.⁴⁰

The purpose of these safe harbors is to define payment practices that will not be subject to criminal prosecution, exclusion, or civil monetary penalties. However, strict compliance with the criteria for each safe harbor is necessary to obtain immunity under these rules and the practices that are protected are very narrow. Therefore, careful reading and assessment is necessary. A reading of these regulations in their entirety shows that certain recurring themes permeate them. First, remuneration or economic benefit given to a referring physician may not be proportionate to or contingent upon the making of a referral or the ordering of a good or service. Second, that remuneration may not exceed the fair market value of the service, property or investment for which the remuneration is given. Third, wherever possible, the parties should sign a written agreement specifying the manner and extent to which the service, property or investment of the referring physician is to be compensated. Finally, that agreement should be for a term of no less than one year. The concept behind these requirements is to avoid a *quid pro quo* arrangement.

As noted above, to comply with a safe harbor and escape enforcement, *all* criteria for the particular safe harbor must be met. However, it is important to note that failure to comply fully with a safe harbor's criteria does not necessarily mean that a particular practice or arrangement violates the Statute. In effect, the practical consequence of not

³⁴56 *Fed. Reg.* 35952 (1991).

³⁵57 *Fed. Reg.* 52723 (1992).

³⁶61 *Fed. Reg.* 2122 (1996).

³⁷64 *Fed. Reg.* 63504 (1999).

³⁸66 *Fed. Reg.* 62979 (2001).

³⁹67 *Fed. Reg.* 60202 (2002).

⁴⁰70 *Fed. Reg.* 38081 (2005).

meeting the requirements for a safe harbor is to leave the party in much the same position as it was prior to the rules, with one notable difference. Because prosecution requires the specific intent to solicit or receive illegal remuneration, the existence of the rules makes it more difficult to assert a defense of lack of intent.

Finally, it should be noted that the final rules rely heavily on *Bay State* for guidance, particularly that "the gravamen of Medicare Fraud is inducement" and that "[T]he statute is aimed at the inducement factor." In other words, relying on *Bay State*, the OIG takes the position that the payment is not the important element. What is important is an *intent to induce*.

An exhaustive review of the safe harbors is beyond the scope of this handout. However, following is a listing of the major categories of practices that are protected. As always, when entering into one of these arrangements, the advice of experienced legal counsel is advisable. One should get good advice for someone who practices in this area and understands its idiosyncrasies. It is almost impossible to completely eliminate risk in this area; however, if those risks can be quantified and the activity is conducted in good faith on the advice of counsel, the risks can be mitigated.

The categories covered by the safe harbors are:

§ Investment Interests

There are two components to the investment interest safe harbor, one for large publicly traded entities and another for certain small entities. There are certain general issues that apply to both.

§ Space and Equipment Rental

§ Personal Services/Management Contracts

§ Employees

§ Group Purchasing Organizations

§ Purchase of a Physician's Practice

§ Referral Services

§ Discounts and Warranties

§ Investment Interests in Rural Areas

§ Investment Interests in Ambulatory Surgical Centers

- § Investment Interests in Group Practices Composed Exclusively of Active Investors
- § Practitioner Recruitment
- § Obstetrician Malpractice Insurance Subsidies
- § Referral Agreements for Specialty Services
- § Cooperative Hospitals Service Organizations
- § Ambulance Restocking

Advisory Opinions and Bulletins

Advisory opinions are published on the Office of Inspector General's website (<http://oig.hhs.gov/fraud/advisoryopinions/opinions.html>). While I will not discuss these opinions in detail, one in particular deserves note. On April 23, 2003, the Office of Inspector General of the Department of Health and Human Services (OIG) published an Advisory Bulletin that has raised concerns throughout the health care industry about the legality of a variety of provider joint ventures.

These joint ventures involve a hospital or other health care provider who decides to expand into a related service line by contracting with an existing provider of that service. The problem, from the OIG's perspective, is that the provider is contracting out the entire operation of a related line of business to what would otherwise be a competitor. The OIG sees the hospital's share of the profits from the new venture constituting remuneration for the referral of the hospital's Medicare/Medicaid patients. According to the OIG, this remuneration may violate the federal Anti-Kickback Statute.

In the Advisory Bulletin, the OIG provides the following examples of potentially problematic contractual arrangements:

A hospital establishes a subsidiary to provide DME. The new subsidiary enters into a contract with an existing DME company to operate the new subsidiary and to provide the new subsidiary with DME inventory. The existing DME company already provides DME services comparable to those provided by the new hospital DME subsidiary and bills insurers and patients for them.

A DME company sells nebulizers to federal health care beneficiaries. A mail order pharmacy suggests that the DME company form its own mail order pharmacy to provide nebulizer drugs. Through a management agreement, the mail order pharmacy runs the DME company's pharmacy, providing personnel, equipment, and space. The existing mail order

pharmacy also sells all nebulizer drugs to the DME company=s pharmacy for its inventory.

There are several common elements cited by the OIG that are typically found in these “problematic arrangements,” including:

- § Owner expands into a related line of business, which is dependent on referrals from, or other business generated by, the Owner=s existing business.
- § Owner neither operates the new business itself nor commits substantial financial, capital, or human resources to the venture.
- § Manager/Supplier is an established provider of the same services as the Owner=s new line of business.
- § Owner and the Manager/Supplier share in the economic benefit of the Owner=s new business.
- § Aggregate payments to the Manager/Supplier typically vary with the value or volume of business generated for the new business by the Owner.

Since the hospital does not commit substantial financial, capital, or human resources to the venture, there is a lack of business risk. The hospital=s primary contribution to the new venture is referrals. In describing suspect arrangements, the Advisory Bulletin points to joint ventures in which the hospital or other provider is not actively involved either as an investor or as an operator. Therefore, the financial benefits of the venture to the hospital or other provider are not a return on investment or labor, but a kickback for patient referrals.

Recent Cases and Settlements Involving the Anti-Kickback Statute

Civil Monetary Penalties (2005):⁴¹

- § Medical Center Hospital, Texas, agreed to pay \$333,500 to resolve its liability under the CMP provisions applicable to kickbacks. The OIG alleged that from December 1, 1998 through November 30, 2001, the hospital leased space to a physician group at a rate below fair market value.
- § A former Chief Executive Officer (CEO) of Good Samaritan Hospital, Nebraska, agreed to pay \$130,000 and to enter into a 3-year integrity

⁴¹DHHS, Office of the Inspector General, *Fraud Abuse and Detection/Enforcement Actions*, “Administration Actions,” 2005.

agreement to resolve his liability under the CMP provisions applicable to kickbacks. The OIG alleged that from September 1994 through October 1999, the former CEO provided financial assistance to a physician in the form of bank loan guarantees, the payment of consultant fees, and the provision of discounted pharmaceuticals, biologicals, supplies, and medical equipment to induce her referral of Medicare beneficiaries requiring cardiology care to the hospital.

- § Home Health Corporation of America (HHCA), Pennsylvania, agreed to pay \$300,000 and to enter into a 5-year integrity agreement to resolve its liability under the CMP provisions applicable to kickbacks. The OIG alleged that from February 1997 through May 1998, HHCA made payments in the form of loans, consulting fees, and monthly space rental payments to six physicians located in Pennsylvania and Florida to induce their referral of Medicare beneficiaries requiring home health services and/or durable medical equipment
- § St. Joseph Mercy-Oakland (SJMO), Michigan, agreed to pay \$4 million to resolve its liability under the CMP provisions applicable to kickbacks and stark law violations. The OIG alleged that SJMO entered into financial arrangements with 14 different physicians and physician groups. The financial arrangements allegedly included office management services, medical equipment, lease and/or purchase agreements, loans, and income guarantees
- § Tender Loving Care Health Care Services, Inc. (TLC), a nationwide home health agency, agreed to pay \$130,000 to resolve its liability under the CMP provisions applicable to false claims and kickbacks. The OIG alleged that one of TLC=s franchisees (Miami Lakes) paid commissions to non-employees who were providing marketing services. TLC allegedly made commission payments for each patient referred to TLC by the independent contractor sales representatives. The payments were allegedly based on the type of services utilized by the referred patients.

Civil Monetary Penalties (2004):⁴²

⁴² DHHS, Office of the Inspector General, *Fraud Abuse and Detection/Enforcement Actions*, “Administration Actions,” 2004.

- § A California physician agreed to pay \$57,500 and to enter into an Integrity Agreement to resolve his liability under the CMP provisions applicable to false claims and kickbacks. The OIG alleged that the physician received free samples of the prostate cancer drug Lupron from Tap Pharmaceutical Products, Inc. and billed at least some of those samples to Medicare and other payers.
- § A Texas physician agreed to pay \$38,941.92 and to enter into an Integrity Agreement to resolve his liability under the CMP provisions applicable to false claims and kickbacks. The OIG alleged that the physician received free samples of the prostate cancer drug Lupron from Tap Pharmaceutical Products, Inc. and billed at least some of those samples to Medicare and other payers.
- § A New Jersey physician agreed to pay \$500,000 and enter into a five-year integrity agreement to resolve his liability under the CMP provisions for violating the Stark Law and the Anti-Kickback Statute. The physician entered into two lease agreements with a home health agency/durable medical equipment supplier to which the physician referred Federal health care program beneficiaries. The OIG alleged that neither lease was commercially reasonable and that both leases were shams to disguise kickbacks paid to the physician in exchange for referrals.
- § Dominican Health Services, d/b/a Holy Family Hospital (Holy Family), Washington, agreed to pay \$270,000 and to maintain its existing compliance program and to undertake certain integrity obligations for a three-year period to resolve its liability under the CMP provisions applicable to kickbacks. The OIG alleged that Holy Family paid remuneration to induce referrals from an entity owned by urologists. The OIG alleged that Holy Family entered into a series of contracts with an entity owned by urologists under which Holy Family paid the entity in excess of fair market value for the lease of a lithotripter and contracted lithotripsy services. The OIG alleged that Holy Family's payments were to induce Federal health care program referrals from the urologists who owned the entity.

Criminal Actions.⁴³

- § In Louisiana, the former owner/administrator of a geriatric psychiatric facility was sentenced to 15 months in prison and ordered to pay \$313,000

⁴³DHHS, Office of the Inspector General, *Fraud Abuse and Detection/Enforcement Actions*, "Criminal Actions," 2004-5.

in restitution for health care fraud and for illegal payment of kickbacks. The man failed to disclose a related party on the facility's 1999 cost report and paid marketers for Medicare referrals. In addition, for receiving illegal kickback payments, a marketer was ordered to pay \$67,000 in restitution.

- § In California, a physician was sentenced to 5 months in prison, 150 days home confinement and ordered to pay \$120,000 in restitution for illegal remuneration. The physician accepted kickbacks in exchange for the use of his provider number, which was used to fraudulently bill Medicare, Medi-Cal and private insurers for services provided by unqualified individuals.
- § In Illinois, a man was ordered to pay a \$10,000 fine for violating the anti-kickback statute. As a sales manager for a large medical equipment distributor, the man provided enteral pumps at no charge in order to induce the purchase of related enteral products and advised nursing homes on how to submit charges to Medicare for the enteral pumps.
- § In Kansas City, in 1999, after a nine week trial in the federal district court, a jury found two physicians and two hospital executives guilty of violating the statute. The physicians were members of a medical group that provided care to patients in nursing homes. Most of these patients were covered by Medicare.

The indictment indicates that these physicians approached several hospitals in the area with the benefits of entering into "consulting agreements" with the medical group. Five hospitals entered into these agreements, but according to the indictment, no consulting duties were ever performed. The conviction of one hospital executive was overturned on appeal, but the conviction of the hospital's president and the two physicians was upheld.

- § In Kentucky, an owner of a durable medical equipment company was sentenced to six months home detention and ordered to pay \$708,000 in restitution for payment of kickbacks. From approximately 1992 to 2002, the man paid kickbacks to a physician and his office manager in return for patient referrals to his company for oxygen and oxygen-related products.

Ohio Law

The prohibition upon kickbacks for referrals under Ohio law arises as a crime relating to insurance. In addition, kickbacks are specifically prohibited in the physician licensing laws, discussed below.

Under Ohio law, it is a crime to knowingly solicit, offer, pay, or receive any kickback or rebate directly or indirectly in exchange for the referral of an individual for health care services or goods for which reimbursement may be made in whole or in part by a health care insurer.⁴⁴ Additionally, physicians can be disciplined by the Ohio State Medical Board for receiving a thing of value in return for a specific referral of a patient to utilize a particular service or business.⁴⁵ Physicians may also be disciplined by the Ohio State Medical Board for violating the ethical code of the American Medical Association which prohibits kickbacks and referral fees. In essence, the AMA prohibitions on kickbacks and referral fees are incorporated into Ohio law.⁴⁶

There is also a prohibition against "fee-splitting." A physician may be disciplined by the Ohio State Medical Board for engaging in "any division of fees or charges, or any agreement or arrangement to share fees or charges, made by any person licensed to practice medicine and surgery . . . with any other person so licensed, or with any other person."⁴⁷

Since these Ohio laws are very similar to the Anti-Kickback Statute, the same methodology would determine whether a particular practice violated these state laws.

V. PHYSICIAN RECRUITMENT

Under the Anti-Kickback Statute, there is a safe harbor for physician recruitment, and under Stark there is an exception to the prohibition on referrals. I will discuss each of these in turn.

The Anti-Kickback Safe Harbor

As was indicated in the discussion above of the Anti-Kickback Statute, many of the cases cited involve payments by hospitals to physicians in violation of the Statute. In discussing physician recruitment in recent compliance guidance, the OIG has this to say:

⁴⁴ORC § 3999.22.

⁴⁵ORC § 4731.22(B)(4)

⁴⁶ORC § 4731.22(B)(14).

⁴⁷ORC § 4731.22(B)(13).

Many hospitals provide incentives to recruit a physician or other health care professional to join the hospital's medical staff and provide medical services to the surrounding community. When used to bring needed physicians to an underserved community, these arrangements can benefit patients. However, recruitment arrangements pose substantial fraud and abuse risk. In most cases, the recruited physician establishes a private practice in the community instead of becoming a hospital employee.⁵⁵ Such arrangements potentially implicate the anti-kickback statute if one purpose of the recruitment arrangement is to induce referrals to the recruiting hospital. Safe harbor protection is available for certain recruitment arrangements offered by hospitals to attract primary care physicians and practitioners to health professional shortage areas (HPSAs), as defined in regulations issued by the Department.⁵⁶ The scope of this safe harbor is very limited. In particular, the safe harbor does not protect (a) recruitment arrangements in areas that are not designated as HPSAs, (b) recruitment of specialists, or (c) joint recruitment with existing physician practices in the area. Because of the significant risk of fraud and abuse posed by improper recruitment arrangements, hospitals should scrutinize these arrangements with care. When assessing the degree of risk associated with recruitment arrangements, hospitals should examine the following factors, among others:

- The size and value of the recruitment benefit. Does the benefit exceed what is reasonably necessary to attract a qualified physician to the particular community? Has the hospital previously tried and failed to recruit or retain physicians?
- The duration of payout of the recruitment benefit. Total benefit payout periods extending longer than three years from the initial recruitment agreement should trigger heightened scrutiny.
- The practice of the existing physician. Is the physician a new physician with few or no patients or an established practitioner with a ready stream of referrals? Is the physician relocating from a substantial distance so that referrals are unlikely to follow or is it possible for the physician to bring an established patient base?
- The need for the recruitment. Is the recruited physician's specialty necessary to provide adequate access to medically necessary care for patients in the community? Do patients already have reasonable access to comparable services from other providers or practitioners in or near the community? An assessment of community need based wholly or partially on the competitive interests of the recruiting hospital or existing physician practices would subject the recruitment payments to heightened scrutiny under the statute.

Significantly, hospitals should be aware that the practitioner recruitment safe harbor excludes any arrangement that directly or indirectly benefits any existing or potential referral source other than the recruited physician. Accordingly, the safe harbor does not protect >>joint recruitment== arrangements between hospitals and other entities or individuals, such as solo practitioners, group practices, or managed care organizations, pursuant to which the hospital makes payments directly or indirectly to the other entity or individual. These joint recruitment arrangements present a high risk of fraud and abuse and have been the subject of recent government investigations and prosecutions. These arrangements can easily be used as vehicles to disguise payments from the hospital to an existing referral sourceC typically an existing physician practiceCin exchange for the existing practice=s referrals to the hospital. Suspect payments to existing referral sources may include, among other things, income guarantees that shift costs from the existing referral source to the recruited physician and overhead and build-out costs funded for the benefit of the existing referral source. Hospitals should review all >>joint recruiting== arrangements to ensure that remuneration does not inure in whole or in part to the benefit of any party other than the recruited physician.⁴⁸

Therefore, it is very important that in recruiting physicians to fall within the parameters of the safe harbor for physician recruitment. That safe harbor provides:

Practitioner recruitment. As used in section 1128B of the Act, Aremuneration@ does not include any payment or exchange of anything of value by an entity in order to induce a practitioner who has been practicing within his or her current specialty for less than one year to locate, or to induce any other practitioner to relocate, his or her primary place of practice into a HPSA [Health Professional Shortage Area] for his or her specialty area, as defined in Departmental regulations, that is served by the entity, as long as all of the following nine standards are met B

(1) The arrangement is set forth in a written agreement signed by the parties that specifies the benefits provided by the entity, the terms under which the benefits are to be provided, and the obligations of each party.

(2) If a practitioner is leaving an established practice, at least 75 percent of the revenues of the new practice must be generated from new

⁴⁸70 FR 4868 (Jan 31, 2005)

patients not previously seen by the practitioner at his or her former practice.

(3) The benefits are provided by the entity for a period not in excess of 3 years, and the terms of the agreement are not renegotiated during this 3-year period in any substantial aspect; provided, however, that if the HPSA to which the practitioner was recruited ceases to be a HPSA during the term of the written agreement, the payments made under the written agreement will continue to satisfy this paragraph for the duration of the written agreement (not to exceed 3 years).

(4) There is no requirement that the practitioner make referrals to, be in a position to make or influence referrals to, or otherwise generate business for the entity as a condition for receiving the benefits; provided, however, that for purposes of this paragraph, the entity may require as a condition for receiving benefits that the practitioner maintain staff privileges at the entity.

(5) The practitioner is not restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her choosing.

(6) The amount or value of the benefits provided by the entity may not vary (or be adjusted or renegotiated) in any manner based on the volume or value of any expected referrals to or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under Medicare, Medicaid or any other Federal health care programs.

(7) The practitioner agrees to treat patients receiving medical benefits or assistance under any Federal health care program in a nondiscriminatory manner.

(8) At least 75 percent of the revenues of the new practice must be generated from patients residing in a HPSA⁴⁹ or a Medically Underserved Area (MUA)⁵⁰ or who are part of a Medically Underserved Population (MUP) all as defined in paragraph (a) of this section.⁵¹

⁴⁹Health Professional Shortage Area (HPSA) is a geographic area designated as having a shortage of primary medical care professionals.

Source: DHHS, HRSA, Bureau of Health Professions .

⁵⁰Medically Underserved Areas (MUA) may be a whole county or a group of contiguous counties, a group of county or civil divisions or a group of urban census tracts in which residents have a shortage of personal health services.

Source: DHHS, HRSA, Bureau of Health Professions.

(9) The payment or exchange of anything of value may not directly or indirectly benefit any person (other than the practitioner being recruited) or entity in a position to make or influence referrals to the entity providing the recruitment payments or benefits of items or services payable by a Federal health care program.⁵²

In summary, this safe harbor protects payments made by entities, including hospitals, needed to attract physicians to rural and urban areas designated by the Health Resources and Services Administration as shortage areas. Unless the hospital is recruiting for a designated area, no safe harbor protection is available. Note that at least 75 percent of the recruited practitioner=s revenue must come from patients residing in the designated area. Also note that the duration of the payments is limited to three years. The types of protected payments, such as income guarantees and moving expenses are not delineated, leaving that to the parties to determine. The safe harbor does not protect payments by hospitals to existing group practices, a prevalent practice in the industry, to encourage them to recruit physicians. It also does not protect payments to retain existing practitioners.

Stark

Under Stark, physician recruitment is included under the exceptions to the referral prohibition related to compensation arrangements. The rule is long and very complicated, and I will not reproduce it here. However, the key components of the rule are as follows:

1. Must be set out in writing and signed by the parties.
2. It cannot be conditioned on referrals.
3. The amount of remuneration cannot be based on the volume or value of referrals.

⁵¹Medically Underserved Populations (MUPs) may include groups of persons who face economic, cultural or linguistic barriers to health care.

Source: DHHS, HRSA, Bureau of Health Professions.

⁵²42 CFR 1001.952(n).

4. There can be no restrictions of the physician establishing privileges or making referrals to any other hospital.
5. The physician must relocate his practice at least 25 miles.
6. At least 75 percent of the physician=s revenues must come from care provided to new patients.
7. Residents and physicians who have been in practice less than one year are eligible for the exception even if they do not move their practices, but the recruited resident or physician must establish his or her medical practice in the geographic area served by the hospital.
8. For payments made either indirectly through payments made to another physician or physician practice, or directly to a physician who joins a physician practice, there are additional conditions:
 - a. The written agreement must also be signed by the party to whom the payments are directly made;
 - b. Except for actual costs incurred by the physician or physician practice in recruiting the new physician, the remuneration is passed directly through to or remains with the recruited physician;
 - c. The costs allocated by the physician or physician practice to the recruited physician can not exceed the actual additional incremental costs attributable to the recruited physician;
 - d. Records of these costs and the passed through amounts are maintained for at least 5 years;
 - e. The remuneration from the hospital shall not to be determined by the volume or value of any actual or anticipated referrals by the physician or the physician practice;
 - f. The physician or physician practice may not impose additional practice restrictions on the recruited physician other than conditions related to quality of care; and
 - g. The arrangement does not violate the anti-kickback statute
9. This exception applies to remuneration provided by a federally qualified health center in the same manner as it applies to remuneration provided by a hospital, so long as the arrangement does not violate the anti-kickback statute.

Recent Caselaw

10. Despite a lot of rhetoric from the Office of the Inspector General relating to recruiting physicians, I could find no caselaw or other enforcement actions within the last three years. However given the comments on the subject in the Compliance Guidance published in January 2005,⁵³ discussed above, the arrangements are clearly under the microscope. Any recruiting activity contemplated should be carefully reviewed by experienced legal counsel.

⁵³70 FR 4868 (Jan 31, 2005)

VI. OTHER FRAUD AND ABUSE LAWS

As part of Health Insurance Portability and Accountability Act (HIPAA), the U.S. Criminal Code was amended to include several new healthcare fraud offenses. A general prohibition was enacted that makes it a crime to knowingly and willfully execute, or attempt to execute, a scheme or artifice: (1) to defraud any healthcare benefit program; or (2) to obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program.⁵⁴ The term "health care benefit program" is defined as "any public or private plan or contract, affecting commerce, under which any medical benefit, item or service is provided to any individual, and includes any individual or entity who is providing a medical benefit, item or service for which payment may be made under the plan or contract."⁵⁵ Penalties for violation of this statute include a fine and/or imprisonment for not more than ten years. However, if the violation results in serious bodily injury,⁵⁶ the imprisonment can be for a period of up to twenty years, and if the violation results in death, the penalty can include imprisonment for any term of years or for life.

In addition, the statute includes provisions for making of false statements and theft or embezzlement. For making a false statement, a person can be subject to a fine and/or imprisonment of up to five years when "such person, in any matter involving a healthcare program: [K]nowingly and willfully (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; or (2) makes any materially false, fictitious, or fraudulent statements or representations, or makes or uses any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry."⁵⁷ Theft or embezzlement related to a healthcare activity can result

⁵⁴ 18 USC § 1347.

⁵⁵ 18 USC § 24(b) (emphasis added).

⁵⁶ For a definition of the phrase "bodily injury," see 18 USC § 1365.

⁵⁷ 18 USC § 1035.

in a fine and/or imprisonment for not more than ten years. However, if the value of the property is less than \$100, the imprisonment is reduced to not more than one year.⁵⁸

This HIPAA provision has been used by the United States Attorney for the Southern District of Ohio to prosecute practitioners for attempting to circumvent insurance restrictions placed on certain areas of practice. In one instance, a chiropractic group was charged with using the services of an M.D. in an M.D.-D.C. relationship to circumvent the restrictions placed on chiropractic care by insurance companies.

In addition to the HIPAA provisions, there is a myriad of laws used by the authorities to prosecute health care fraud. Following is a listing of some of those fraud and abuse laws that are pertinent. The list is not intended to be exhaustive. If you have questions about any of these laws, please call me at the number listed below.

- § Medicare or Medicaid False Claims Act 42 U.S.C. ' 1320a-7b(a)(1)-(5).
- § False Representations of Institutional Conditions. 42 U.S.C. ' 1320a-7b(c).
- § Excessive Charges. 42 U.S.C. ' 1320a-7b(d).
- § False Claims (Civil Sanction). 42 U.S.C. ' 1320a-7a(a)(1)-(3).
- § Mandatory Exclusion. 42 U.S.C. 1320a-7(a)(1)-(2).
- § Permissive Exclusion. 42 U.S.C. 1320a-7(b)(1)-(14).
- § False Claims. 18 U.S.C. 287.
- § RICO. 18 U.S.C. ' 1961.

⁵⁸ 18 USCA ' 669.

VII. OTHER COMPLIANCE ISSUES

The HIPAA Security Rules took effect on April 21, 2005⁵⁹. Some estimates indicate that as high as 35 percent of healthcare providers are not ready to implement these standards.⁶⁰ You should be sure that figure does not include you. You should contact your legal counsel and arrange for a HIPAA security consultant, working under the direction of legal counsel, to work with you to bring you into compliance. A security consultant can perform the required risk analysis, develop the mandated policies and train your staff to implement them. It is important, however, that this work be directed by legal counsel to protect the attorney-client privilege.

You never know when you will be selected for a HIPAA Audit, so it is imperative that you are prepared. The penalties for non-compliance can be severe. They include the imposition of civil monetary penalties of \$100 per violation, not to exceed \$25,000 in any one calendar year. In a recent case in Washington State⁶¹, Richard W. Gibson of SeaTac, Washington was sentenced to 16 months in prison, three years of supervised release, and more than \$9,000 in restitution for wrongful disclosure of individually identifiable health information for economic gain. According to the press release:

GIBSON admitted that he obtained a cancer patient's name, date of birth and social security number while GIBSON was employed at the Seattle Cancer Care Alliance, and that he disclosed that information to get four credit cards in the patient's name. GIBSON also admitted that he used several of those cards to rack up more than \$9,000 in debt in the patient's name. GIBSON admitted he used the cards to purchase various items, including video games, home improvement supplies, apparel, jewelry, porcelain figurines, groceries and gasoline for his personal use. GIBSON was fired shortly after the identity theft was discovered.

In a videotaped victim statement played in court, the cancer patient described how he had "lost a year of life both mentally and physically

⁵⁹The HIPAA Security Rules can be found in their entirety at 68 FR 8834, Feb. 20, 2003.

⁶⁰ *American Medical News*, April 18, 2005, p. 1.

⁶¹Press Release, United States Attorney=s Office, Western District of Washington, November 5, 2004.

dealing with the stress" of having his identity stolen and dealing with banks, credit card companies and collection agencies.

It is important to note that at the time of this criminal act, the HIPAA Security Rules were not in effect. What happens if an employee perpetrator takes such information in a medical practice that is not HIPAA compliant, now that the Rules are in place, is still an unknown. Would the practice also be held liable and possibly fined or worse? Since such a case has not been adjudicated, it remains to be seen. However, you do not want to become the test case. It is important that you become compliant now.

While an authoritative new ruling by the Justice Department sharply limits the government's ability to prosecute people for criminal violations, this does not protect health care providers. The criminal penalties, the department said, apply to insurers, doctors, hospitals and other providers -- but not necessarily their employees or outsiders who steal personal health data. Nevertheless, it does apply to insurers, doctors, hospitals and other providers, and employees acting in the scope of their employment are agents of these providers. The criminal penalties include a \$250,000 fine and 10 years in prison for the most serious violations.

The standards are divided into either required or addressable implementation specifications. They are in three sections, Administrative Safeguards, Physical Safeguards and Technical Safeguards. Each section is made up of several standards. In summary, they mandate that you take the following actions:

- § Perform a HIPAA Risk Analysis
- X Develop Patient Information Security Policies and Procedures:
Administrative, Physical, and Technical Safeguards
- X Train your staff and implement the required policies

In essence, your entity should have a written risk analysis that addresses all of the elements of the rules and a written set of information technology policies and procedures that comply with the required standards. And you should have documented evidence of training for your staff and how the policies have been implemented.

VIII. CONCLUSION

Getting paid is important to health care providers. And receiving what you are entitled to is even more important; however, you only want to receive what is coming to you. The health care fraud and abuse laws are very complicated and complex. Nevertheless, you are responsible to ensuring that you are in compliance with them. Failure to do so can be hazardous to your freedom and your pocketbook.

To say that application of the health care fraud and abuse laws is less than clear would be a gross understatement. Nevertheless, structuring ventures and conducting business so that one is as close as possible to compliance guidance, the exceptions and the safe harbors will mitigate the risk of an enforcement action by the OIG or other law enforcement agencies.

One should get good advice for someone who practices in this area and understands its idiosyncrasies. It is almost impossible to completely eliminate risk; however, if those risks can be quantified and the activity is conducted in good faith on the advice of counsel, the risks can be mitigated.

