

**HOSPITAL/PHYSICIAN COMPENSATION
UNDER STATE AND FEDERAL
ANTI-KICKBACK LAWS**

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HOSPITAL/PHYSICIAN COMPENSATION UNDER STATE AND FEDERAL ANTI-KICKBACK LAWS

A. INTRODUCTION

Because of the ever increasing focus on how health care dollars are spent, all aspects of health care spending are hot topics, especially physician compensation based on the premise that physicians hold the keys to all of the dollars in the health care bank.

The most straight forward way to state the problem, and which understates the actual complexity of the issue, is that physicians cannot receive compensation directly or indirectly based on their referrals for medical services where those services could possibly be reimbursed by federal or state health care dollars. It sounds like a simple enough proposition but trying to implement that principle has resulted in extremely complex payment arrangements and full-time work for many an attorney.

These materials will discuss the two major federal statutory frameworks that restrict physician compensation based on referrals, the relationship of those frameworks with the Federal False Claims Act and three additional state statutory prohibitions on the payment of compensation for referrals. To a large extent, these various statutory frameworks overlap but they each have their own idiosyncrasies and traps. In addition to those five basic statutory frameworks, these materials also discuss two other legal and regulatory matters that are important to physician compensation, namely the corporate practice of medicine doctrine and Medicare reassignment rules. These materials attempt to provide a

basic discussion of the framework of the various statutory and regulatory rules, with appropriate and helpful references and citations.

B. FEDERAL ANTI-KICKBACK STATUTE

The Medicare Anti-kickback statute is the mother of all anti-kickback/anti-rebate statutes. It is codified at 42 U.S.C. 1320a-7b. The Anti-kickback statute is a broadly worded statute that makes it a crime to pay or receive remuneration of any kind for referrals or services compensable under any federal or state health care program. More specifically, the Anti-kickback statute makes it a felony, punishable by up to five years in prison and a \$25,000 fine, to “knowingly and willfully” solicit, receive, offer or pay any remuneration in return for (1) referring or arranging for services payable by any federal or state health care program, or (2) purchasing, leasing ordering or arranging for any goods, facilities or services which may be paid for in whole or in part by any federal or state health care program. Another sanction available under the statute is exclusion of any person or entity from participation in the Medicare program. Additionally, the Balanced Budget Act of 1997 added civil monetary penalties for violations of the Anti-kickback statute in amounts up to \$50,000 per violation and assessments equal to not more than three times the amount of remuneration paid under the arrangement. (See 42 U.S.C. 1320a-7a(7)).

To restate the basic prohibition of the statute, if a payment of any kind, direct or indirect, is being made where at least one purpose of the payment is to influence referrals, purchasing, leasing, or to furnish anything that can be paid for by Medicare or Medicaid, then both the person/entity paying and the person/entity

receiving the payment can be charged with a felony or be subject to civil monetary penalties. The most important built in safeguard in this statute, as far as providers are concerned, is that the payment or receipt of payment must be made “knowingly and willfully.” How courts ultimately interpret this requirement will determine just how much protection it affords providers.

The Ninth Circuit Court of Appeals has interpreted the “knowingly and willfully” requirement to mean that an individual charged with violating the Anti-kickback statute must (1) know that the law prohibited the conduct at issue, and (2) engage in that conduct with the specific intent of violating the statute. That is a very high standard for the government enforcer to overcome. However, courts in other federal circuits have ruled that the statute is violated if only one purpose of the payment is to influence or induce referrals, even in the absence of a specific knowledge of the statute and a specific intent to violate it. So long as the Ninth Circuit’s current interpretation remains in place, providers located in the Ninth Circuit can enter into various arrangements with a higher degree of confidence than providers located outside of the Ninth Circuit. Until the U.S. Supreme Court addresses this split of opinion on the definition of “knowingly and willingly” there will be no definitive answer.

The primary enforcer of the Anti-kickback statute is the Office of the Inspector General of the Department of Health and Human Services (the “OIG”). In addition to enforcing the statute, the OIG is charged with developing “safe harbors” to the statute and responding to requests for advisory opinions related to the statute.

The Anti-kickback statute contains a few exceptions where the statute will not apply, including bona fide employment relationships. That exception simply states that the statute will not apply to: “Any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.”

In addition to this exception, the OIG has adopted by regulation several so called “safe harbors.” If the facts of a particular situation meet all of the requirements of any of the safe harbors, then that situation/transaction will not be found to violate the Anti-kickback statute. However, the fact that a given situation does not meet all the requirements of a safe harbor does not mean the situation violates the statute. Instead, it simply means that you must apply a normal Anti-kickback statutory analysis to the situation to see if it complies. This is an important aspect of federal anti-kickback analysis because it is frequently impossible to meet all of the requirements of any given safe harbor.

Prior to November 1999, the OIG had promulgated 13 safe harbors. In 1994, the OIG published a proposed rule clarifying several of the existing and proposed new safe harbors. In November 1999, the OIG finally published a final rule adopting several clarifications to the existing safe harbors and adopting eight new safe harbors. (See 64 FR 63518 (Nov. 19, 1999)). The current safe harbors under the Anti-kickback statute are as follows:

- (a) Investment interests – (i) large entity; (ii) small entity; and (iii) entity in under-server area;
- (b) Space rental;
- (c) Equipment rental;

- (d) Personal services and management contracts;
- (e) Sale of practice;
- (f) Referral services;
- (g) Warranties;
- (h) Discounts;
- (i) Employees;
- (j) Group purchasing organizations;
- (k) Waiver of beneficiary co-insurance and deductible amounts;
- (l) Increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by health plans;
- (m) Price reductions offered to health plans;
- (n) Practitioner recruitment;
- (o) Obstetrical malpractice insurance subsidies;
- (p) Investments in group practices;
- (q) Cooperative hospital services organizations;
- (r) Ambulatory surgery centers;
- (s) Referral agreements for specialty services;
- (t) Price reductions offered to eligible managed care organizations; and
- (u) Price reductions offered by contractors with substantial financial risk to managed care organizations.

These safe harbors are codified at 42 CFR 1001.952. The discount, employees, waiver of coinsurance, and group purchasing safe harbors are all also statutory exceptions, set forth in 42 U.S.C. 1320a-7b(b)(3). The safe harbor

regulations related to these exceptions attempt to clarify the exception. It is important to remember that there are exceptions and, if applicable, the statutory prohibitions do not apply to these situations.

The most relevant safe harbor to physician compensation arrangements (besides the employee exception/safe harbor) is the personal services and management contracts safe harbor, which requires that:

- (1) the agreement be in writing and signed by the parties;
- (2) the agreement cover all of the services between the two parties for the term of the agreement and specify the services to be provided by the physician;
- (3) if the services are on a part-time basis, then the agreement must specify the exact schedule for the services;
- (4) the term of the agreement is for not less than one year;
- (5) the aggregate compensation paid is set in advance, is consistent with fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be paid under Medicare or a state health care program;
- (6) the services performed do not involve the counseling or promotion of a business arrangement or other activity that violates state or federal law; and
- (7) the aggregate services called for in the agreement must not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

Several of these requirements make compliance with this safe harbor difficult, if not impossible, for most physician compensation arrangements, especially those between a physician and a hospital. First, the personal services safe harbor requires that all of the services provided by the physician to the entity (e.g., a hospital, clinic, group practice, etc.) must be covered under the agreement.

These preclude compliance with this safe harbor if a physician has multiple compensation arrangements with the same entity. Second, the agreement must set the aggregate compensation in advance, which prevents the use of formulas or hourly rates. Another important twist, is that the OIG believes that agreements cannot have “without cause” termination provisions and comply with this requirement.

When all of those requirements are laid on top of a typical physician compensation agreement (other than employment arrangements), the result is a form of agreement that is of very little practical use in structuring relationships that adequately account for modern health care business realities and that properly align physician and entity financial incentives.

The personal services safe harbor is the most important safe harbor in relation to financial arrangements that address payment for services rendered. Several other of the safe harbors (space and equipment rental, investment interests, physician recruitment, investments in group practices, and ambulatory surgery centers) have important impacts on other types of physician financial arrangements. Discussing all of these safe harbors is beyond the scope of these materials. However, there are several general principles that attorneys should look for when faced with these other types of arrangements. In planning for compliance with the Anti-kickback statute, the existence of any of the following factors in a proposed transaction or agreement should always trigger red flags: if an agreement requires one of the parties to refer patients to the other party or some other specific entity; investment or participation interests that are tied to the

volume or value of referrals; provisions requiring the expulsion of participants or cancellation of agreements if a party does not refer patients to other parties or the new entity; disproportionate returns on investment; and guaranteed returns on investments. In addition, if one of the parties is motivated by a desire to secure a flow of referrals, and makes statements indicating that motivation, an intent to violate the statute may be found. In any case where any of these factors are identified, a provider should undertake a more detailed analysis to ensure the arrangement does not violate the Anti-kickback statute.

The Anti-kickback statute requires the OIG to provide advisory opinions regarding the application of the statute to specific situations, upon request. The request must meet several lengthy requirements which these materials will not address here, except to state that the requestor must reimburse the OIG for the cost of providing the opinion. Opinions are only binding on the requestor and will take a minimum of 60 days to obtain from the OIG. The OIG will not address issues regarding the fair market value of any particular arrangement. The OIG's advisory opinions, along with various other items of useful information, are available on the OIG's web site at www.dhhs.gov/progorg/oig/advopn/index.htm. As of this writing, the statute requiring the OIG to provide advisory opinions expired (or sunsetted). The OIG is still issuing opinions related to requests made prior to the sunset date. There is an initiative by many health care providers (apparently supported by the OIG) to reauthorize the advisory opinion process.

C. FEDERAL STARK LAW A/K/A ETHICS IN PATIENT REFERRALS ACT

If the Anti-kickback statute is the mother of all anti-rebate statutes, then the Stark Law is the Gordian Knot of such laws. Referred to by the name of its Congressional sponsor, Representative Pete Stark of California, the official name of the statute is the Ethics in Patient Referrals Act. Originally enacted in 1989 (“Stark I”) to apply to a physician’s referrals for clinical laboratory services to entities with which the physician had a financial relationship, the Stark Law was expanded in 1993 (“Stark II”) to cover ten other “designated health services.” The Stark Law is codified at 42 U.S.C. 1395nn.

Unlike the Anti-kickback statute, Health Care Finance Administration (HCFA) has authority for promulgating regulations attempting to explain the Stark Law. HCFA did not publish final regulations implementing Stark I until 1995. 60 FR 41914 , codified at (42 CFR 411 *et. seq.*), Aug. 14, 1995. In January 1998, HCFA finally published proposed regulations Stark II. 63 FR 1659, Jan. 9, 1998. Then on January 4, 2001, HCFA published “Phase I” of the final Stark II regulations. 66 FR 856, Jan. 4, 2001. However, the effective date of Phase I of the Stark II regulations was delayed until January 4, 2002. Phase I does not address several of the most important Stark Law exceptions, including the employment exception, personal services exception and recruiting exception. However, several of the concepts addressed in Phase I will carry over and apply to the exceptions yet to be addressed in Phase II. HCFA promised the Phase II regulations shortly, but after extending the comment period for the Phase I

regulations until June 4, 2001, it appears that “shortly” may mean sometime after January 2002.

The Stark Law prohibits a physician from making a referral to an entity for the furnishing of designated health services (or DHS) for which Medicare or Medicaid would otherwise pay if the physician has a direct or indirect financial relationship with the entity, unless a specific exception applies. Each of the underlined words has a material definition for purposes of the Stark Law. In order to fully understand the breadth of the Stark Law, you must understand the definitions, which are discussed in detail below. The most important aspect of this statute, however, is the lack of an intent requirement. Under this statute, if a financial arrangement does not meet all of the requirements of one of the exceptions, the financial arrangement violates the statute, regardless of any intent by either party to the arrangement to do so.

The penalties under this statute are harsh. Penalties under the Stark Law are civil in nature. They include denial of payment for claims made under arrangements that violate the law, refunds of all payments that were made under such improper arrangements, civil fines of up to \$15,000 for each claim for a service that a person knew was made under a prohibited arrangement, and civil fines of up to \$100,000 for each arrangement where the principal purpose was to circumvent the law. Additionally, a violation can result in both the entity and physician being excluded from federally funded health care programs. While both health care entities and physicians are potentially at risk for violations of the

Stark Law, it is not clear which of the sanctions will apply to the physician that makes a prohibited referral.

Finally, some courts have now held that a violation of the Stark Law can result in liability under the federal False Claims Act. The federal False Claims Act prohibits any person from submitting a “false” claim for payment to the government. Violations of the act are punished by up to treble damages and can be prosecuted by third-party whistle blowers. The argument is that a claim submitted under an arrangement that violates the Stark Law is a “false” claim.

To date, there has been minimal enforcement of the Stark Law. However, various governmental enforcers (*e.g.*, the OIG and Department of Justice) have begun asserting, at least informally, that they will assert violations of the Stark Law in health care fraud investigations. Entities and physicians should be ready to face full Stark enforcement atmosphere in the very near future.

As discussed in full below, the Stark Law has far reaching implications and impacts virtually all physician financial arrangements. The medical and legal professions have widely criticized both the breadth of the act and the lack of binding guidance. In 1999, two bills were introduced in Congress that could limit the scope of the statute. Neither of those bills had much success.

Definitions

To understand the Stark Law, one must understand the basic definitional terms. The most critical terms are defined below.

Referral - The term “referral” means (1) any request by a physician for an item or service, including the request by a physician for a consultation with another physician (and any test or procedure ordered by or performed by or under the supervision of the other physician), or (2) any request for

or establishment of a plan of care that includes the provision of any DHS. A referral does not include any DHS personally performed by the physician; however a DHS is not personally performed if it's provided by any other person, including but not limited to, the referring physician's employees, independent contractors or group practice members.

Entity – An “entity” is any type of business structure or organization that provides “designated health services.”

Designated Health Services or DHS - There are eleven statutorily defined “designated health services”:

- Clinical laboratory services;
- Physical therapy services;
- Occupational therapy services;
- Radiology services, including magnetic resonance imaging, computerized 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, and prosthetic devices and supplies;
- Home health services;
- Outpatient prescription drugs; and
- Inpatient and outpatient hospital services.

As part of Phase I of the Stark II final rules, HCFA has defined many of the DHS (including radiology services) by CPT codes and published those codes in the Federal Register and Code of Federal Regulations.

Financial Relationship - means either a direct or indirect (i) “compensation arrangement” or (ii) “ownership or investment interest.” A financial relationship does not need to involve designated health services or Medicare/Medicaid patients.

Direct Compensation Arrangement - any arrangement involving payment of remuneration between the physician (or immediate family member of the physician) and an entity.

Indirect Compensation Arrangement – the final regulations set forth a very complicated test for determining when an indirect compensation arrangement exists. There are three factors: (1) there must be an unbroken chain of financial relationships (compensation arrangements or ownership interests) between the entity and the physician; (2) the referring physician receives aggregate compensation from the person or entity in the chain with which the physician has a direct financial relationship that varies

with, or otherwise reflects the volume or value of referrals or other business generated between the referring physician and the DHS entity; and (3) the DHS entity has knowledge of or acts with reckless regard as to requirement (2).

Ownership or Investment Interest – Phase I of the final regulations clarify that an indirect ownership interest can pierce through several layers of holding companies; however, an indirect ownership interest will only trigger the Stark prohibition if the entity has actual knowledge of or acts in reckless disregard or deliberated ignorance of the fact that the referring physician (or an immediate family member) has some ownership or investment interest in the entity.

Physician – The term physician used in the statute includes any immediate family member of physician, *i.e.*, spouse, child or parent.

Volume or Value of Referrals – compensation does not take into account the volume or value of referrals if the compensation is fair market value for services actually rendered and does not vary during the course of the agreement in any manner that takes into account referrals for DHS. “Per use” or “unit of service” based payment arrangements are allowed under this standard.

Set In Advance – compensation is “set in advance” if the aggregate compensation or a time based unit of service is set in advance in the initial agreement between the parties in sufficient detail such that it can be objectively verified. The payment amount must be fair market value for services actually rendered not taking into account the volume or value of referrals or the business generated by the referring physician at the time of the initial agreement. **Note:** percentage based compensation are not set in advance if they are based on fluctuating or indeterminate measures such as revenue, collections or expenses. This is a change set forth in Phase I.

It is also critical to understand that the statutory prohibition only applies to referrals for DHS covered by Medicare.

Exceptions

For a physician compensation arrangement to comply with the Stark law, it must fall within one of the specific exceptions set forth in the statute or regulations. The following are some of the exceptions that have specific

application to typical physician compensation arrangements. Most of the discussion will involve the In-Office Ancillary Services exception and the definition of a group practice.

In-Office Ancillary Services

Referrals for designated health services (other than durable medical equipment (except for infusion pumps), and parenteral and enteral nutrients, equipment and supplies) do not violate the Stark Law if:

- a. the services are furnished
 - (i) personally by the referring physician, member of the referring physician's group practice or individuals under the supervision of the referring physician or group member; and
 - (ii) in a centralized building or a building in which the physician or the physician's group furnishes substantial physician services (unrelated to the furnishing of DHS); and
- b. the services are billed by the physician performing or supervising the services, by the group practice or by an entity wholly owned by the performing physician or such group practice.

While Phase I does not yet have the full force of law, there are several principles in Phase I that parties to physician transactions should consider.

- "Same building" means a structure or combination of structures that share a single street address, but does not include a mobile van or trailer.
- "Centralized building" means all or part of a building (including a mobile van or trailer) that is owned or leased on a full-time (24 hours per day, seven days per week) basis by a group and that is used exclusively by the group.
- Physicians qualify as "members" of a group only during the time they furnish services to patients of the group practice that are furnished through the group and are billed in the name of the group.

Another key to the application of the In-Office Ancillary exception is the definition of "group practice." The statute currently defines a group practice as:

a. A group of two or more physicians organized in a legally recognized entity:

(i) in which each physician who is a member of the group provides substantially the full range of services which the physician routinely provides;

(ii) for which substantially all of the services provided by group members are provided through the group and are provided and billed under a group billing number;

(iii) in which the expenses and income are distributed according to a “previously determined” method;

(iv) in which no physician member receives, directly or indirectly, compensation based on the “volume or value of referrals” by the physician member (unless allowed by the special rules); and

(v) in which physician members personally conduct no less than 75% of the physician/patient encounters of the group.

b. Special Rules - Profits and productivity bonuses: A physician member may be paid a share of overall profits of the group, or a productivity bonus based on services personally performed (or incident to services personally performed) so long as such bonus is not directly related to the volume or value of referrals of the physician member.

The Phase I contains extensive changes and supplements to the definition of a group, including the following:

- A group must consist of one single legal entity, which must consist of two or more individual physicians (including a solo physician that employs one or more physicians).
- “Members of the Group” include owners and employees, but not independent contractors; however, independent contractors will be considered “physicians in the group” for purposes of providing necessary supervision under the In-Office Ancillary exception.
- As a result of the proposed changes, at least 75% of the total patient care services must be furnished by members of the group.
- “patient care services” includes any services addressing the medical needs of specific patients, including time spent training group staff

members or performing administrative or management tasks. The key is that the activities benefit the operation of the group practice.

- A “previously determined” method for distributing costs and revenues must be set and in place prior to the receipt of payment for the services giving rise to the overhead expense or producing the income.
- A group can adopt cost center and location based accounting providing that the group meets certain definitions (*e.g.*, a minimum of five physicians in the cost center).
- A group cannot compensate physician members based on the volume or value of referrals for DHS paid by Medicare or Medicaid.
- Productivity bonuses are allowed, if they do not take into account referrals for DHS.
- Sharing of overall profits is ok, so long as they are not determined in a manner that directly relates to the volume or value of DHS by the physician.

Based on the promulgation of Phase I, groups should begin an in depth review of their compensation methodologies to ensure compliance by January 2002. While it is possible (likely) that the effective date will be further delayed, it is also highly likely that the final rule’s version of the group practice definition and in-office ancillary exception will remain substantially similar to that set forth in Phase I.

Bona Fide Employment

This exception allows for any amount paid by an employer to a physician (or immediate family member of a physician) who has a bona fide employment relationship with the employer for the provision of services if:

- (i) the employment is for identifiable services;
- (ii) the amount of the remuneration under the employment is consistent with the fair market value of the services and is not based on the volume of referrals by the employee physician;

(iii) the remuneration is provided pursuant to a written agreement which would be commercially reasonable even if no referrals were made to the employer; and

(iv) the employment relationship meets any other applicable regulations or requirements protecting against program or patient abuse.

The comments to the proposed regulations include the following in relationship to the bona fide employment exception:

- An employee can be paid a productivity bonus only if the bonus is not directly related to the volume or value of the employee's own referrals (the same standard as for productivity bonuses under the group practice definition).

While Phase I did not specifically address this exception, hospitals and groups should look to the definitions of "volume or value" and "referrals" in Phase I and apply them to employment relationships. Also, interested parties should take care to review whether Phase II (when published) attempts to impose the "set in advance" requirement on employment relationships which would prohibit most percentage based compensation arrangements.

Personal Services Arrangements

Personal services arrangements will not be considered "compensation arrangements" if they meet the following requirements:

(i) the arrangement is in writing, signed by the parties, and specifies the services covered by the arrangement;

(ii) the arrangement covers all of the services provided by the physician (or immediate family member) to the entity;

(iii) the aggregate services do not exceed what is commercially reasonable for the legitimate business needs of the entity;

(iv) the term of the agreement is for at least one year;

(v) the compensation is set in advance, does not exceed fair market value, and does not take into account the volume or value of any referrals (unless it qualifies as a “physician incentive plan”) or other business generated between the parties;

(vi) the services do not involve the counseling or promotion of any business arrangement that violates any state or federal law; and

(vii) the arrangement meets other requirements or regulations protecting against fraud and abuse.

This exception does contain the “set in advance” requirement. Thus, any existing arrangements that use percentage based compensation likely will not comply with this exception, unless this issue is addressed and corrected in Phase II. All entities and physician groups should keep their eyes open for Phase II and if it does not appear before January 4, 2002, any personal services arrangement with percentage based compensation should be amended or terminated.

Other potentially applicable exceptions:

- Equipment and Space Rentals;
- Remuneration unrelated to provision of designated health services;
- Recruiting;
- Isolated transactions; and
- Payments made by a physician.

None of these exceptions were addressed in Phase I.

New Exception – Fair Market Value

Phase I includes a new exception for compensation arrangements. The exception only covers any compensation arrangement from an entity to a

physician (or immediate family member) or group of physicians for services rendered by the physician:

- (i) the agreement is in writing, signed by the parties, and covers identifiable items and services;
- (ii) the agreement specifies the time frame, which can be for any period, provided the parties can only enter one agreement for the same items or serviced during the course of one year (or if for less than one year, can only be renewed on the same compensation terms during that year);
- (iv) the agreement specifies the compensation that will be provided under the arrangement which has been set in advance, is consistent with fair market value, and does not take into account the volume or value of any referrals or other business generated by the referring physician;
- (v) the agreement involves a transition that is commercially reasonable and furthers the legitimate business purposes of the parties; and
- (vi) the agreement meets a safe harbor under the Anti-kickback statute, is the subject of a favorable advisory opinion, or otherwise complies with the Anti-kickback statute.

As with the personal services exception, the set in advance requirement will prohibit the use of percentage compensation arrangements. Additionally, parties relying on this exception should be aware that it only applies to arrangements where compensation is flowing from an entity to a physician.

New Exception – Indirect Compensation Arrangement

Just as HCFA created a new, specific (if completely baffling) definition of indirect compensation arrangements, it also created a new exception for these arrangements. Unfortunately, the new exception is equally (if not more) confusing than the definition, due in large part to the fact that the two both use the volume or value standard as key elements. The exception has three elements that virtually parallel the elements of the fair market value exception:

- (1) the compensation received by the referring physician from the entity in the chain with whom he/she has a direct relationship must be fair market value for the services actually provided to that entity, not taking into account the volume or value of referrals or other business generated by the referring physician and the DHS entity;
- (2) the compensation arrangement must be set out in writing, signed, specify the services to be rendered and be commercially reasonable; and
- (3) not violate the anti-kickback statute or any laws or regulations governing billing or claims submissions.

It remains to be seen if HCFA will attempt to clarify this exception (and the definition) in Phase II. We certainly hope so.

Other New Exceptions

There are several other new, relatively minor exceptions worthy of note which these materials will not go into any detail regarding. They include:

- Non-monetary compensation up to \$300;
- Medical staff incidental benefits;
- Implants at ASCs; and
- Compliance training.

Joint Ventures

The Stark statute does not clearly answer the question of whether a hospital/physician joint venture violates the Stark Law. In Phase I, HCFA attempts to clarify the issue by stating that an ownership or investment interest in a subsidiary is not an ownership nor investment in the parent corporation, nor in any other subsidiary, unless the subsidiary corporation itself holds an interest in the parent or such other subsidiary. While this seems to clarify the issue, HCFA casts some doubt on this analysis by virtue of its definition of an indirect compensation arrangement (*i.e.*, the unbroken chain language). HCFA further

clouds the issue by stating that some ownership or investment interests may create compensation arrangements.

Assuming that HCFA's first statement should be taken at its word, this still does not end the inquiry. Although the mere fact a hospital/physician joint venture may not itself create an ownership interest in the hospital, what the joint venture does and its method of operation may create a financial arrangement with the hospital indirectly. Under Stark, a "hospital" is defined to include not only the legal entity holding the hospital license, but also any separate subsidiary or other related entity that performs services for the hospital's patients and for which the hospital bills. Thus, if the joint venture provides hospital services under arrangements with hospital, the joint venture itself may be deemed part of the hospital. All potential hospital – physician joint ventures must under go careful, independent review to ensure that the structure complies with Stark Law.

Advisory Opinions

The Stark Law requires HCFA to provide advisory opinions regarding the Stark statute upon request. The request must meet several lengthy requirements which will not be addressed here, except to state that the requestor must reimburse HCFA for the cost of providing the opinion. Opinions are only binding on the requestor and will take a minimum of 90 days to obtain from HCFA. HCFA will not address issues regarding the fair market value of any particular arrangement. To date, only one Stark advisory opinion has been published by HCFA. Advisory opinions are available on HCFA's web site at www.hcfa.gov/regs/aop/default.htm.

Relationship of Stark Law and Medicare Anti-kickback Statute

One of the more interesting issues related to the Stark Law, is how various parties (the OIG, HCFA, Department of Justice, etc.) will attempt to apply each statute in the context of the other. While several of the Stark Law exceptions are similar to Anti-kickback statute safe harbors, none have identical provisions. One question that has arisen is whether compliance with the Anti-kickback statute is a prerequisite to meeting the requirements of a Stark exception (and vice versa). Given that HCFA has in Phase I inserted specific requirements that the arrangement comply with the Anti-kickback statute, the answer appears to be yes.

The OIG, in the November 19, 1999 final safe harbor rule, did make some comments on the correlation of the two laws. Specifically, several commentators suggested that arrangements that were permitted under the Stark Law should receive protection under the Anti-kickback statute, or that the safe harbors be made consistent with the Stark exceptions. The OIG declined. First, the OIG noted that the Stark Law is civil in nature while the Anti-kickback statute provides for criminal penalties. The OIG acknowledged that compliance with both sets of laws might be burdensome, but felt it would be inappropriate to conform one set of laws to the other. The OIG believes there is clear Congressional intent that the two statutes be treated separately. Finally, the OIG believes that arrangements that may comply with the per se requirements of a Stark exception, may still violate the Anti-kickback statute if there is an intent to induce referrals and, therefore, that it would be inappropriate to link compliance in the two statutes.

D. FALSE CLAIMS ACT

The Federal False Claims Act prohibits a person from “knowingly” submitting claims or making a false record or statement in order to secure that a false or fraudulent claim is paid by the federal government. A person found to have violated this statute is liable for a civil penalty of not less than \$5,000 and not more than \$10,000, plus three times the amount of damages sustained by the federal government.

The statute specifically provides that the terms “knowing” and “knowingly” mean that a person “(1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information.” Therefore, no specific intent to defraud is required.

Under the False Claims Act, civil actions must be brought within six years after the date of the violation or within three years after the date when material facts are known or should have been known by the government, but in no event more than ten years after the date on which the violation was committed.

The Federal False Claims Act also authorizes “qui tam” actions to be brought on behalf of the government by a private party having direct knowledge of the fraud. 31 U.S.C. § 3730(b). These private parties, who are often referred to as “qui tam relators,” may share in the monetary recovery paid as part of the eventual settlement or disposition of the action whereby the qui tam relator’s recovery is dependent upon whether the government has intervened in the action. The private party commences such an action in federal court by filing the

complaint and relevant documentation “under seal” and serving these documents on the DOJ only. Initially, the defendant is not served. The DOJ, by statute, then has at least 60 days to evaluate whether to pursue the action. If good cause can be shown, the government may obtain an extension of time beyond the 60-day period. This may result in a qui tam complaint pending for an extended period of time before the defendant is even aware of the action. During this time period, the government will conduct its own investigation of the fraud alleged in the complaint. If, based upon its investigation, the government decides to proceed with the action, the government has the primary responsibility for prosecuting the action and the qui tam relator has the right to remain as a party to the action. If the government decides not to proceed with the action, the qui tam relator may elect to proceed on his or her own with the action against the defendant, however the government may be permitted at a later time to intervene in the case.

The constitutionality of the qui tam provisions of the Federal False Claims Act recently has been questioned. Specifically, in May 2000, the Supreme Court issued its long awaited decision in Vermont Agency of Natural Resources v. United States regarding the constitutionality of private actions under the Federal False Claims Act.

The following are some sample false claims theories applicable to health care providers:

- Billing for Items or Services Not Actually Rendered
- Providing Medically Unnecessary Services
- Upcoding/DRG Creep/Capitation Misclassification
- Waiver of Coinsurance and Deductibles

- Medicare Secondary Payor Issues
- Unbundling/Fragmentation
- Filing False Cost Reports
- Bootstrapping Anti-Kickback and Stark Law Violations into False Claims Actions
- Payments to Induce Reduction or Limitation of Services
- Payments to Teaching Hospitals
- DRG Payment Window
- Investigational Devices
- Quality of Care Issues

In addition to the Federal False Claims Act, Washington has a statute titled “Health Care False Claims”. This act applies to false claims made to both governmental and private payers. While this act has not received wide spread attention, its potential applicability is huge given that it does apply to private payers. A copy of the statute is set forth in Appendix 3.

E. STATE ANTI-KICKBACK AND STARK STATUTES

Pursuant to requirements in federal Medicare and Medicaid statutes, Washington state adopted by statute the Stark physician referral ban and the federal Anti-kickback statute. For purposes of the state Medicaid program, or Medical Assistance program as it is referred to in Washington, the statutes were codified at RCW 74.09.240. Additionally, Washington has adopted the anti-kickback provisions as part of its workers’ compensation program. See RCW 51.48.280.

As to the referral ban, the Washington statute authorizes the Department of Social and Health Services to adopt by rule subsequent amendments to the federal Stark Law as well as providing that the state referral ban does not apply to cases covered by a general exception in the federal Stark statute. This raises the question of whether exceptions promulgated by HCFA and set forth in the Code of Federal Regulations (rather than the federal statute) will also apply as exceptions to the state Stark Law. This question was answered in a letter from the State Attorney General's Office to Valley Medical Center dated September 30, 1998 which stated in sum that exceptions promulgated by regulation to the federal Stark Law would be recognized as exceptions to the state Stark Law.

Other questions raised by the state version of the referral ban include the fact that the state statute does not expressly preclude the entity that received the prohibited referral from billing for that referral. Additionally, the state law fails to include a penalty provision in the case of a violation.

The state Anti-kickback law is even more confusing. Rather than reference the federal Anti-kickback law or regulations, the state Anti-kickback law simply restates the operative provision of the federal law. However, the state versions omits one key element: it fails to include the intent requirement. None of the federal Anti-kickback law's safe harbors are referred to or recognized in the state Anti-kickback law; although, two of the statutory exceptions are included. Thus, the question arises whether any federally created safe harbors will be recognized in a state enforcement action.

To date, this state statute (including both the referral ban and the Anti-kickback law) has been completely ignored by state enforcement officials (the Attorney General, Department of Health, Department of Social and Health Services and county prosecutors).

Although there is a general lack of interest regarding these statutes, practitioners should not ignore them when advising physician clients. While enforcers may ignore these provisions, there is always the possibility that a private party could assert violations of the statute as part of a False Claims Act claim or a sword to avoid contractual obligations.

F. STATE ANTI-REBATE LAW

Washington's Anti-rebate statute (Ch. 19.68 RCW) consists of one of the longest and most poorly worded sentences in the entire Revised Code of Washington. The statute can be reduced to three main elements: The Anti-Rebate statute prohibits (1) the payment of a profit, (2) in connection with the furnishing of medical diagnosis, treatment or service, and (3) to a person licensed by the state to practice medicine and surgery. The Anti-rebate statute contains two explicit exceptions: (1) for diagnostic services where the physician discloses her/his financial interest and provides a list of alternative providers, and (2) for services furnished by a physician group. See RCW 19.68.010.

The Attorney General and county prosecutors have not enforced this statute with much enthusiasm. The risk under this statute runs to physicians who, if they are found to have violated the statute, would be guilty of a misdemeanor. Additionally, under RCW 19.68.020 and .030, it is unprofessional conduct for a

physician to violate the Anti-rebate statute. To add to the confusion, RCW 19.68.030 purports to make any splitting of fees for medical care, treatment, or diagnosis grounds for a licensure action. Professional penalties include the revocation or suspension of a physician's license.

Interpretations

Day v. Inland Empire Optical, 76 Wn.2d 407 (1969).

This is the only reported Washington case addressing the Anti-rebate statute. The case involved five ophthalmologist who owned an optical dispensing company. The physicians' offices were upstairs and their optical dispensing company was on the ground floor of the same building. Foot traffic exiting from the upstairs physicians' offices was channeled through the optical dispensing company downstairs. The upstairs offices also had signs directing patients to take their prescriptions downstairs if they desired.

The court found that: (1) the physicians ownership (by stock) was compensation under the Anti-rebate statute; (2) the location of the optical store in relation to the physicians' offices, as well as the signs and the physicians' customary practices were "referrals" to the optical store under the statute; and (3) the physicians upstairs were not supervising the licensed opticians downstairs.

The court went on to state:

Defendant doctors, we believe, have a right to own stock in a dispensing optical company provided they neither directly nor indirectly either verbally or in writing, or by sign, symbol or gesture, or by physical arrangement of their offices, refer their patients to the optical company, or indicate in any way their hopes that the patient take his prescription there.

Day v. Inland Empire Optical, 76 Wn.2d 407, 420. The court declined the request of numerous friends of the court to undertake a broader, definitive analysis of the statute and limited it to the specific facts before it. Thus, the court did not address the “furnishing” prong of the Anti-rebate statute.

AGO 1975 No. 24, (11/28/75)

Following the Day opinion, the Attorney General (AG) issued its first of three letter opinions regarding the statute. First, the AG addressed whether the statute prohibits physician ownership of certain entities. The AG answered by stating that the Anti-rebate statute does not prohibit a licensed physician from owning part or all of a nursing home in which the physician is responsible for patient care. “Simply stated, it is not ownership that is restricted by the law but rather the physician’s financial benefit derived from referring or supplying patients.”

Next, the AG discussed the difference between the “referral” prong and the “furnishing prong”. Regarding the referral prong, the AG made the following statements:

Provided that there is no referral, a physician may receive a financial benefit when the institution in which the physician has a financial interest furnishes services or goods that are not prescribed by the physician. The physician can also receive a financial benefit for services performed by him or rendered by a licensed employee of the physician.

Conversely, however, a physician is not entitled to receive a financial benefit from the services or goods furnished to patients of an institution in which the physician holds some ownership interest when the physician prescribes the services or goods that the institution furnishes to the patient, or when the physician refers the patient to the institution.

The AG opinion also states in regard to the “furnishing” prong that if the physician or a physician owned institution is “furnishing” medical supplies or services to a patient (even one not “referred”) the “physician can only furnish such supplies or services at the actual cost thereof.”

AGO 1988 No.28 (11/14/88)

The next AG letter opinion addressed a referral arrangement between an optometrist and ophthalmologist. The first question posed was whether an agreement by an optometrist to refer surgery patients to an ophthalmologist with the understanding that the optometrist would provide post-operative care violated the Anti-rebate statute or RCW 18.130.180(21). (The opinion also addressed issues related to the Medical Disciplinary Board’s authority but that is not relevant to this discussion.)

In addressing this question, the AG looked at the intent of the statute (to guard against the receipt of secret profits through dealings with patients) to determine how to interpret the statute. With that intent in mind, the AG looked beyond the referral itself to determine if the patients were paying for anything other than services actually rendered by the referring professional. In this context, the AG opined that neither the optometrist nor the ophthalmologist would be receiving a profit for services other than those services actually rendered by them and for which they were licensed. “The referral does not, by itself, result in any hidden or inflated charges, unnecessary surgery or care, or profits for services not rendered by the referring professional.”

AGO 1992 No. 30, (12/22/92)

The final AG letter opinion addressing this statute was issued in late 1992. The three questions asked were: (1) does the Anti-rebate statute prohibit physicians from referring their patients to an infusion therapy company in which the physicians are shareholders; (2) does the answer to (1) change if the physicians supervise the services provided at the infusion therapy company; and (3) does Anti-rebate statute prohibit a physician from receiving a fee from the therapy company for services provided to the company's patients?

Relying on Day, the AG opined that physician stock holders in an infusion therapy company would receive financial benefit from any referrals they made to the company, and, therefore, such referrals would violate Anti-rebate statute.

As to the second question, the AG concluded that to escape Anti-rebate statute, a physician would have to exercise actual and exclusive control over the performance of the infusion company's employees.

Question three was answered in the negative, i.e., the Anti-rebate statute does not prohibit an infusion therapy company from paying a physician for services, so long as the physician actually performs the services, is paid fair market value, and does not receive duplicate payment from additional sources. As to this third question, the facts do not seem to contemplate that the physician being paid for services has an ownership interest in the company. If the physician did, then the "furnishing" prong addressed in AGO 1975 No. 24 would apply. Under that opinion, the physician would be prescribing and furnishing services and supplies, and therefore could not make a profit on those services and supplies.

In the July 1992 issue of *Health Law News*, Philip Bane reported that the Department of Health (the “Department”) denied a Certificate of Need (CON) for a physician-owned outpatient kidney dialysis center, in part, because there was no “reasonable assurance” the project would not violate the Anti-rebate statute. In a June 10, 1998 phone conference with a CON program analyst from the Department, the analyst stated that the case referred to was later reviewed and approved with the imposition of some conditions designed to facilitate the intent of the Anti-rebate statute.

The analyst went on to state that most of the ASC CON applications that she had processed or seen were owned by hospitals or physicians. The Department does want the Anti-rebate statute addressed in a CON application (i.e., how will the applicant comply with the intent of the statute) but the Department does not take the position that the project must strictly comply with the statute. She stated that acceptable methods for addressing the Anti-rebate/referral issue included: disclosure by physicians to their patients of the physician’s ownership interest; providing a list of effective, available alternative providers; and compliance with the Stark Law exceptions and Anti-kickback law safe harbors (i.e., compliance with the diagnostic exception in the Anti-rebate statute).

Because of the lack of enforcement activity and the absence of adequate interpretative guidelines, providers and practitioners are often times operating in the dark regarding the proper interpretation of the statute as they attempt to structure provider agreements and develop new health care facilities. Ultimately,

providers must undertake a risk analysis realizing that it is often impossible to comply with the literal terms of the Anti-rebate statute. Thus, providers are forced to determine whether it is an acceptable level of risk to rely on the Anti-rebate statute's statement of intent and hope that if an arrangement complies with the federal Stark Law and the Anti-kickback statute, then it should fall within the parameters of acceptable conduct the Anti-rebate statute intended to allow. So long as there is no enforcement activity, this may indeed be a risk acceptable to most providers.

In undertaking this risk analysis, providers need to keep in mind two important caveats. First, the Day case was a private action brought by competitors of an ophthalmologist group. In that case, the court agreed with the plaintiff competitors that the defendant ophthalmologists were violating the statute and ordered the defendants to cease the offending conduct. Thus, although the attorney general, county prosecutors, and the medical quality assurance commission may have no interest in enforcing the Anti-rebate statute, a private party/competitor still may be able to use it to force a provider to stop whatever conduct the private party claims is in violation of the statute. Secondly, the Washington State Legislature considered, but failed to adopt, a state version of the False Claims Act in the 1998 session. If the Legislature does adopt a state false claims act, then there may very well be financial incentives for private parties to bring actions under the false claims act to enforce the Anti-rebate statute. Whether that eventuality ever occurs will depend on the Legislature and the actual content of a state false claims act.

G. CORPORATE PRACTICE OF MEDICINE

The corporate practice of medicine doctrine is based upon concerns that a corporation employing a physician would threaten the ability of the physician to freely exercise medical judgment, intrude on the physician/patient relationship, and share improperly in physician fees. Corporate practice of medicine issues may arise in the course of a physician compensation arrangement, depending on whether an entity will be employing a physician, and the type of entity employing the physician.

Relevant Statutes

Washington has no statute that expressly prohibits a hospital from employing a physician. Several statutes, however, are relevant to the issue.

Washington's Uniform Disciplinary Act prohibits unlicensed practice defined as: "Practicing a profession or operating a business identified in 18.130.040 without holding a valid . . . license to do so." RCW 18.130.020(6)(a).

Another statute provides that "no person may practice or represent him or herself as practicing medicine without first having a valid license to do so." RCW 18.71.021.

The Professional Service Corporation Act grants authority for the corporate practice of medicine, provided all the shareholders are licensed to practice medicine. RCW 18.100.020(2), .050.

The Medical Malpractice Prevention Act of 1986, RCW 70.41.230, contemplates the hiring of physicians by hospitals, stating that: "prior to . . . hiring

a physician, a hospital or facility approved pursuant to this chapter shall request from the physician . . . the following information”

Case Law

The case of Morelli v. Ehsan, 110 Wn.2d 555, 564 (1988) addressed the issue of corporate practice of medicine, holding that a physician and a non-physician accountant could not operate a medical clinic as partners. Authorities are divided on whether the case should be extended to prohibit hospitals from employing physicians or whether it is limited to prohibiting the unauthorized practice of medicine by a layperson in a partnership. Many states recognizing the corporate practice of medicine doctrine have provided exceptions for nonprofit and governmental institutions, whose boards are responsible to their communities; however, Washington has not.

Proposed Legislation

Legislation has been proposed to clarify the corporate practice of medicine doctrine in Washington. In the 1998 Legislative session, the Legislature passed a bill that abrogated the corporate practice of doctrine. However, Governor Locke vetoed that bill and the Legislature either did not have the votes or chose not to override the veto. The Governor’s stated reason for vetoing the bill was that enforcement agencies such as the FBI asked to retain the doctrine because it provided a helpful tool in the fight against fraud and abuse. The issue is likely to reemerge in a future legislative session.

As with the state Anti-rebate statute, state enforcers have generally ignored this doctrine. However, private parties have used the doctrine to gain

advantages in private relationships, as was the case in Morelli. More recently, a prominent automobile insurance company has started to use the doctrine to avoid payment for physician therapy services provided to its insureds, where the insurance company believes that the entity providing the physical therapy services are not organized in compliance with the doctrine. Other insurance companies are considering taking this same stance. Thus, compliance with the doctrine is something that should be considered in all physician compensation arrangements.

H. MEDICARE REASSIGNMENT

Under the federal Medicare statute, a physician cannot reassign her/his right to receive payment from Medicare, unless a specific exception applies. This is an important issue because (depending on the physician specialty) an average of 35% of patients are covered by Medicare.

The exceptions to this prohibition are for assignment to the physician's employer; a facility (e.g., a hospital); and an organized health care delivery system or clinic. It is important to ensure that a proposed physician compensation arrangement complies with these rules because failure to do so can result in: termination by HCFA of a physician's Medicare participation agreement; criminal penalties – fine of not more than \$2000 or imprisonment of not more than six months or both; and delay/withholding of payment from HCFA.

I. APPENDICES

1. WASHINGTON ANTI-KICKBACK STATUTES

RCW 51.48.280 Kickbacks, bribes, and rebates-- Representation fees-- Criminal liability--Exceptions.

(1) Any person, firm, corporation, partnership, association, agency, institution, or other legal entity, that solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind:

(a) In return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this chapter; or

(b) In return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any goods, facility, service, or item for which payment may be made in whole or in part under this chapter; shall be guilty of a class C felony. However, the fine, if imposed, shall not be in an amount more than twenty-five thousand dollars, except as authorized by RCW 9A.20.030.

(2) Any person, firm, corporation, partnership, association, agency, institution, or other legal entity, that offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person:

(a) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made, in whole or in part, under this chapter; or

(b) To purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any goods, facility, service, or item for which payment may be made in whole or in part under this chapter; shall be guilty of a class C felony. However, the fine, if imposed, shall not be in an amount more than twenty-five thousand dollars, except as authorized by RCW 9A.20.030.

(3) A health services provider who (a) provides a health care service to a claimant, while acting as the claimant's representative for the purpose of obtaining authorization for the services, and (b) charges a percentage of the claimant's benefits or other fee for acting as the claimant's representative under this title shall be guilty of a gross misdemeanor. However, the fine, if imposed, shall not be in an amount more than twenty-five thousand dollars, except as authorized by RCW 9A.20.030.

(4) Subsections (1) and (2) of this section shall not apply to:

(a) A discount or other reduction in price obtained by a provider of services or other entity under this chapter if the reduction in price is

properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under this chapter; and

(b) Any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.

(5) Subsections (1) and (2) of this section, if applicable to the conduct involved, shall supersede the criminal provisions of chapter 19.68 RCW, but shall not preclude administrative proceedings authorized by chapter 19.68 RCW.

RCW 74.09.240 Bribes, kickbacks, rebates--Self- referrals--Penalties. Criminal liability--Exceptions.

(1) Any person, including any corporation, that solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind

(a) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under this chapter, or

(b) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any goods, facility, service, or item for which payment may be made in whole or in part under this chapter, shall be guilty of a class C felony; however, the fine, if imposed, shall not be in an amount more than twenty-five thousand dollars, except as authorized by RCW 9A.20.030.

(2) Any person, including any corporation, that offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person

(a) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made, in whole or in part, under this chapter, or

(b) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any goods, facility, service, or item for which payment may be made in whole or in part under this chapter, shall be guilty of a class C felony; however, the fine, if imposed, shall not be in an amount more than twenty-five thousand dollars, except as authorized by RCW 9A.20.030.

(3) (a) Except as provided in 42 U.S.C. 1395nn, physicians are prohibited from self-referring any client eligible under this chapter for the following designated health services to a facility in which the physician or an immediate family member has a financial relationship:

(i) Clinical laboratory services; (ii) Physical therapy services; (iii) Occupational therapy services; (iv) Radiology including magnetic resonance imaging, computerized axial tomography, and

ultrasound services; (v) Durable medical equipment and supplies; (vi) Parenteral and enteral nutrients equipment and supplies; (vii) Prosthetics, orthotics, and prosthetic devices; (viii) Home health services; (ix) Outpatient prescription drugs; (x) Inpatient and outpatient hospital services; (xi) Radiation therapy services and supplies.

(b) For purposes of this subsection, “financial relationship” means the relationship between a physician and an entity that includes either:

(i) An ownership or investment interest; or (ii) A compensation arrangement. For purposes of this subsection, “compensation arrangement” means an arrangement involving remuneration between a physician, or an immediate family member of a physician, and an entity.

(c) The department is authorized to adopt by rule amendments to 42 U.S.C. 1395nn enacted after July 23, 1995.

(d) This section shall not apply in any case covered by a general exception specified in 42 U.S.C. Sec. 1395nn.

(4) Subsections (1) and (2) of this section shall not apply to:

(a) a discount or other reduction in price obtained by a provider of services or other entity under this chapter if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under this chapter, and

(b) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.

(5) Subsections (1) and (2) of this section, if applicable to the conduct involved, shall supersede the criminal provisions of chapter 19.68 RCW, but shall not preclude administrative proceedings authorized by chapter 19.68 RCW.

2. RCW CHAPTER 19.68 – REBATING BY PRACTITIONERS OF HEALING PROFESSIONS

RCW 19.68.010 Rebating prohibited--Disclosure--List of alternative facilities.

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.

[1993 c 492 § 233; 1973 1st ex.s. c 26 § 1; 1965 ex.s. c 58 § 1. Prior: 1949 c 204 § 1; Rem. Supp. 1949 § 10185-14.]

RCW 19.68.020 Deemed unprofessional conduct.

The acceptance directly or indirectly by any person so licensed of any rebate, refund, commission, unearned discount, or profit by means of a credit or other valuable consideration whether in the form of money or otherwise, as compensation for referring patients to any person, firm, corporation or association as set forth in RCW 19.68.030, constitutes unprofessional conduct.

[1965 ex.s. c 58 § 2; 1949 c 204 § 2; Rem. Supp. 1949 § 10185-15.]

RCW 19.68.030 License may be revoked or suspended.

The license of any person so licensed may be revoked or suspended if he has directly or indirectly requested, received or participated in the division, transference, assignment, rebate, splitting or refunding of a fee for, or has directly or indirectly requested, received or profited by means of a credit or other valuable consideration as a commission, discount or gratuity in connection with the furnishing of medical, surgical or dental care, diagnosis or treatment or service, including x-ray examination and treatment, or for or in connection with the sale, rental, supplying or furnishing of clinical laboratory service or supplies, x-ray services or supplies, inhalation therapy service or equipment, ambulance service, hospital or medical supplies, physiotherapy or other therapeutic service or equipment, artificial limbs, teeth or eyes, orthopedic or surgical appliances or supplies, optical appliances, supplies or equipment, devices for aid of hearing, drugs, medication or medical supplies or any other goods, services or supplies prescribed for medical diagnosis, care or treatment, except payment, not to exceed thirty-three and one-third percent of any fee received for x-ray examination, diagnosis or treatment, to any hospital furnishing facilities for such examination, diagnosis or treatment.

[1965 ex.s. c 58 § 3. Prior: 1949 c 204 § 3; Rem. Supp. 1949 § 10185-16.]

RCW 19.68.040 Declaration of intent.

It is the intent of this article [chapter], and this article [chapter] shall be so construed, that persons so licensed shall only be authorized by law to charge or receive compensation for professional services rendered if such services are actually rendered by the licensee and not otherwise: PROVIDED, HOWEVER, That it is not intended to prohibit two or more licensees who practice their profession as copartners to charge or collect compensation for any professional services by any member of the firm, or to prohibit a licensee who employs another licensee to charge or collect compensation for professional services rendered by the employee licensee.

[1949 c 204 § 4; Rem. Supp. 1949 § 10185-17.]

3. HEALTH CARE FALSE CLAIMS ACT

CHAPTER 48.80 HEALTH CARE FALSE CLAIM ACT

Sections

- 48.80.010** Legislative finding--Short title.
48.80.020 Definitions.
48.80.030 Making false claims, concealing information--Penalty--
Exclusions.
48.80.040 Use of circumstantial evidence.
48.80.050 Civil action not limited.
48.80.060 Conviction of provider, notification to regulatory agency.

48.80.010 Legislative finding--Short title.

The legislature finds and declares that the welfare of the citizens of this state is threatened by the spiraling increases in the cost of health care. It is further recognized that fraudulent health care claims contribute to these increases in health care costs. In recognition of these findings, it is declared that special attention must be directed at eliminating the unjustifiable costs of fraudulent health care claims by establishing specific penalties and deterrents. This chapter may be known and cited as “the health care false claim act.”

[1986 c 243 § 1.]

48.80.020 Definitions.

Unless the context clearly requires otherwise, the definitions in this section apply throughout this chapter.

- (1) “Claim” means any attempt to cause a health care payer to make a health care payment.
- (2) “Deceptive” means presenting a claim to a health care payer that contains a statement of fact or fails to reveal a material fact, leading the health care payer to believe that the represented or suggested state of affairs is other than it actually is. For the purposes of this chapter, the determination of what constitutes a material fact is a question of law to be resolved by the court.
- (3) “False” means wholly or partially untrue or deceptive.
- (4) “Health care payment” means a payment for health care services or the right under a contract, certificate, or policy of insurance to have a payment made by a health care payer for a specified health care service.

(5) “Health care payer” means any insurance company authorized to provide health insurance in this state, any health care service contractor authorized under chapter 48.44 RCW, any health maintenance organization authorized under chapter 48.46 RCW, any legal entity which is self-insured and providing health care benefits to its employees, and any insurer or other person responsible for paying for health care services.

(6) “Person” means an individual, corporation, partnership, association, or other legal entity.

(7) “Provider” means any person lawfully licensed or authorized to render any health service.

[1995 c 285 § 25; 1986 c 243 § 2.]

NOTES: Effective date--1995 c 285: See RCW 48.30A.900.

48.80.030 Making false claims, concealing information--Penalty--Exclusions.

(1) A person shall not make or present or cause to be made or presented to a health care payer a claim for a health care payment knowing the claim to be false.

(2) No person shall knowingly present to a health care payer a claim for a health care payment that falsely represents that the goods or services were medically necessary in accordance with professionally accepted standards. Each claim that violates this subsection shall constitute a separate offense.

(3) No person shall knowingly make a false statement or false representation of a material fact to a health care payer for use in determining rights to a health care payment. Each claim that violates this subsection shall constitute a separate violation.

(4) No person shall conceal the occurrence of any event affecting his or her initial or continued right under a contract, certificate, or policy of insurance to have a payment made by a health care payer for a specified health care service. A person shall not conceal or fail to disclose any information with intent to obtain a health care payment to which the person or any other person is not entitled, or to obtain a health care payment in an amount greater than that which the person or any other person is entitled.

(5) No provider shall willfully collect or attempt to collect an amount from an insured knowing that to be in violation of an agreement or contract with a health care payor to which the provider is a party.

(6) A person who violates this section is guilty of a class C felony punishable under chapter 9A.20 RCW.

(7) This section does not apply to statements made on an application for coverage under a contract or certificate of health care coverage issued by an insurer, health care service contractor, health maintenance organization, or other legal entity which is self-insured and providing health care benefits to its employees.

[1990 c 119 § 11; 1986 c 243 § 3.]

48.80.040 Use of circumstantial evidence.

In a prosecution under this chapter, circumstantial evidence may be presented to demonstrate that a false statement or claim was knowingly made. Such evidence may include but shall not be limited to the following circumstances:

(1) Where a claim for a health care payment is submitted with the person's actual, facsimile, stamped, typewritten, or similar signature on the form required for the making of a claim for health care payment; and

(2) Where a claim for a health care payment is submitted by means of computer billing tapes or other electronic means if the person has advised the health care payer in writing that claims for health care payment will be submitted by use of computer billing tapes or other electronic means.

[1986 c 243 § 4.]

48.80.050 Civil action not limited.

This chapter shall not be construed to prohibit or limit a prosecution of or civil action against a person for the violation of any other law of this state.

[1986 c 243 § 5.]

48.80.060 Conviction of provider, notification to regulatory agency.

Upon the conviction under this chapter of any provider, the prosecutor shall provide written notification to the appropriate regulatory or disciplinary agency of such conviction.

[1986 c 243 § 6.]

4. USEFUL LINKS

American Health Lawyers
Association

<http://www.healthlawyers.org/>

Office of the Inspector General

<http://www.dhhs.gov/progorg/oig/index.htm>

OIG Advisory Opinions
(Anti-kickback)

<http://www.hhs.gov/progorg/oig/advopn/index.htm>

OIG Compliance Guidance
specifically, Guidance for
Individual and Small Group
Physician Practices

<http://oig.hhs.gov/modcomp/index.htm>

HCFA – Main Site

<http://www.hcfa.gov/>

HCFA Advisory Opinions (Stark)

<http://www.hcfa.gov/regs/aop/default.htm>

Washington State's
Medicare Part B Carrier

<http://www.bcbsnd.com/medweb/>

National Practitioner Data Bank &
Healthcare Integrity & Protection
Data Bank

<http://www.npdb-hipdb.com/>

Washington State Office
of the Insurance Commissioner

<http://www.insurance.wa.gov/>

Washington State Health Care
Authority

<http://www.wa.gov/hca/>

Washington State Department of
Health

<http://www.doh.wa.gov/>

Washington State Medical Quality
Assurance Commission

<http://198.187.0.42/hsqa/hpqad/MQAC/default.htm>

5. PHYSICIAN COMPENSATION ISSUE/COMPLIANCE CHECK LIST

1. Parties
Physician
Immediate family member of physician
Healthcare facility or entity
Related entities
Person receiving (directly or indirectly) funds from state or federal health care program
2. Term of the Agreement
Minimum of one year
Is there a termination without cause provision?
Is there an evergreen clause?
Is there automatic amendment/termination in case of change in law/enforcement action?
3. Description of Services
All the services provided by the parties must be specified in the agreement
4. Aggregate Services
Agreement should address all of the services provided by the parties to each other; or
Cross reference other agreements for services between the parties (including immediate family members and closely related entities)
5. Commercially Reasonable
Amount of services should not exceed what is necessary to meet the commercially reasonable business needs of the parties
6. Compensation
Aggregate compensation set in advance
Compensation formula set in advance
Total compensation not in excess of fair market value
Not based on volume or value of referrals for designated health

- services
- If the entity is tax exempt, and the physician is a “disqualified person,” has the procedure to establish the intermediate sanctions fair market value presumption been followed?
7. Referrals
- Are there referrals between the parties?
- Evidence of intent to induce referrals?
- Requirement (directly or indirectly) to make referrals?
- Does arrangement contemplate referrals to entity owned by one of the parties or a related entity?
- Are referrals for designated health services?
- Are referrals for services paid for (in whole or part) by state or federal healthcare program?
8. Billing Practices
- Who will provide billing services?
- Have proper assignment forms been completed?
- If Medicare reassignment is occurring, is an exception met?
- Is there potential for double B&O tax?
- How is billing service compensated?
9. Compliance Plans
- Do one or both parties have a compliance plan?
- Does either party need a compliance plan?
- Are there methods for physician’s to ensure proper coding?
10. Ownership Interests
- Set at fair market value?
- Distributions proportionate to interest?
- Control proportionate to interest?