

**A GUIDE TO CAPTIVE INSURERS AND  
PHYSICIAN PROFESSIONAL LIABILITY INSURANCE SUBSIDIES**

**Paul E. Knag  
Louis B. Todisco  
Murtha Cullina LLP**

**177 Broad Street  
Stamford, CT 06901  
Tel: (203) 653-5400  
Fax: (203) 653-5444**

**Michael Maglaras  
Principal  
Michael Maglaras & Company**

**60 Long Ridge Road, Suite 202  
Stamford, CT 06902  
Tel: (203) 348-6100  
Fax: (203) 348-6101**

**I. INTRODUCTION**

**A.** The professional liability (“malpractice”) insurance crisis has received a good deal of publicity. The inability of some health care organizations and many individual physicians to obtain adequate professional liability insurance coverage at an affordable cost has resulted in organizations sometimes going without liability insurance coverage.

1. Some physicians have either ceased or restricted their practices (e.g., ob/gyn physicians restricting their practice to gynecology) limiting public access to many physician services.
2. Further evidence of the crisis in obtaining affordable insurance coverage is provided by the actions of state legislatures which have proposed, and in some cases enacted, measures designed to make malpractice insurance more affordable. For example, various state legislatures, and the Congress, have considered the implementation of limits on the recovery of “non-economic” damages in malpractice lawsuits.

**B.** Substantial increases in the cost of malpractice insurance have sometimes resulted in hospitals considering whether to subsidize malpractice premiums for physicians in a situation where a physician(s) may otherwise cease or limit the physician’s practice paying a portion of the physician’s malpractice payment may ensure that needed services are available to the public.

**C.** Another measure which health care organizations have employed to address the rising cost of professional liability insurance has been the organization of “captive” insurance companies. There are a number of different types of captive insurance companies in the medical realm.

1. Captives organized by a hospital to insure hospital claims only.

2. Captives organized by group of hospitals to insure multiple hospitals and other institutional providers.
  - a. Examples of where hospitals use the same captive as their private attendings but do not share risk with them
  - b. Captives where there is shared risk between the hospital and its voluntary attending medical staff.

**D.** Captive profile.

1. Captive insurance companies are often formed to insure a particular organization or group of organizations or individuals.
2. A captive insurance company may have a single owner or a limited group of owners who are often the primary insureds.
3. A captive insurance company is a bona fide insurance company which performs most or all of the activities of a commercial insurance company. Depending on how it is structured and the parties which it is organized to insure, a captive insurance company may:
  - a. determine the organizations or individuals which it wishes to insure;
  - b. review applications and engage in insurance underwriting;
  - c. set premiums for different classes of insureds;
  - d. determine the level of reserves needed to pay claims;
  - e. establish investment policies;
  - f. develop hospital and risk management programs and protocols;
  - g. retain counsel for its insureds; and
  - h. monitor, manage, and settle claims and litigation.

**E.** A captive insurance company may be able to effect cost savings and offer lower physician premiums through lower overhead costs.

1. A captive may also, because of the concentration on a limited number of insureds, perhaps with ties to the sponsoring organization, be in a position to develop and implement effective educational and risk management programs which may serve to limit losses and control premiums.
2. Also, if the captive insures individuals and organizations which may be sued in a single lawsuit, a captive may effect additional savings by requiring a joint defense in appropriate cases, hire one lawyer rather than multiple lawyers and control the settlement decisions both for the individual physician involved as well as the organizational defendants.

3. Primarily because of these features, captive insurance carriers typically are able to offer lower premium costs to their insureds than commercial alternatives can. A captive may also be able to offer insurance coverage in situations where professional liability insurance coverage may not be available from the commercial market.

**F.** There are a number of legal and regulatory issues which must be considered when a hospital or other health care organization seeks to provide some relief to physicians by reducing the physician's cost of malpractice insurance either through a direct payment of some of the cost or through the formation of a captive insurance company which insures both the healthcare organization and those voluntary attending physicians on its medical staff, premiums generally lower than those available commercially.

1. In this latter situation, where a hospital sponsored captive insures both the hospital and physicians, questions may arise as to whether the insured physicians are paying fair market value for the insurance coverage which they are receiving. Said differently, a question may arise as to whether the health care organization may be subsidizing the malpractice insurance coverage of the physicians, and if so, whether the arrangement is justifiable.
2. There are at least three areas of law which must be considered.
  - a. the illegal remunerations/anti-kickback law;
  - b. the Stark law; and
  - c. if a tax-exempt organization is involved, issues related to the sponsoring organization's tax-exempt status.

There are also certain Medicare reimbursement rules relating to captives.

There may also be state or foreign law and rules, including insurance law and state "little Stark" and "little anti-kickback" laws which are beyond the scope of this paper.

We will address below some of the legal issues presented to health care organizations seeking to subsidize malpractice premiums of physicians or to form or operate captive insurance companies under these laws.

## **II. DIRECT SUBSIDIES OF MALPRACTICE INSURANCE PREMIUMS FOR PHYSICIANS**

### **A. The Federal Anti-Kickback Statute.**

1. Paying a portion of a physician's malpractice insurance premiums may well implicate the federal anti-kickback statute, 42 USC § 1320a-7b, at least where the physician is in a position to refer patients to the hospital, but by regulation and by OIG letters, such payments are permitted in certain circumstances.

2. The Federal Anti-Kickback Statute: An Overview. The anti-kickback statute prohibits soliciting, receiving, offering or paying any remuneration in return for referrals of patients and for other activities. The question which may arise is whether the health care organization is subsidizing the cost of the insurance in order to induce referrals from the insured physicians. The statute states, in pertinent part:

**B. Illegal remunerations**

- (1) whoever knowingly and willfully 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 a Federal health care program, or
  - (b) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program. Shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.
- (2) whoever knowingly and willfully 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 a Federal health care program, or
  - (b) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program. Shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

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42 U.S.C. § 1320a-7b (emphasis added). Subsequent paragraphs of the statute set forth exceptions to sections (1) and (2) quoted above, including, but not limited to, exceptions for: amounts paid by an employer to an employee and payment practices specified as safe harbors by DHHS.

3. While the anti-kickback statute is broadly worded, it is an intent based statute. A person violates the statute only if he/she “knowingly and willfully” solicits, receives, offers, or pays any remuneration for referrals of patients or some other purpose prohibited by the statute.
  - a. This statute has been interpreted to include any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9<sup>th</sup> Cir. 1989); United States v. Greber, 760 F.2d 68 (3<sup>rd</sup> Cir., cert. denied, 474 U.S. 988 (1985)).
  - b. The consequences of a violation of this statute are serious. A conviction under the statute may result in a fine, imprisonment and will lead to automatic exclusion from Federal health care programs, including the Medicare and Medicaid programs. Even absent a criminal conviction, the OIG may initiate administrative proceedings to impose civil monetary penalties on a party and/or to exclude such party from participation in Federal health care programs. See 42 U.S.C. § 1320a-7(b)(7), 1320a-7a(a)(7).
4. OIG Authorities – Safe Harbor Provisions. Because of the breadth of the statute, Congress has required the United States Department of Health and Human Services (“DHHS”) to promulgate regulations specifying payment practices (“safe harbors”) which are not prohibited by the statute. The safe harbors promulgated by the OIG set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. (A payment practice which does not fall within a safe harbor does not necessarily violate the statute; such arrangements are evaluated on a case-by-case basis.)
  - a. There is no safe harbor which addresses malpractice insurance subsidization generally. However, there is a safe harbor which addresses obstetrical malpractice insurance subsidies. See 42 C.F.R. § 1001.952(o). This provision states that as used in the anti-kickback statute, the term “remuneration” does not include any payment made by a hospital or other entity that is providing malpractice insurance (including a self-funded entity), where such payment is used to pay for some or all of the costs of malpractice insurance premiums for a practitioner (including a certified nurse-midwife as defined . . .) who engages in obstetrical practice as a routine part of his or her medical practice in a primary care HPSA, as long as seven requirements are met:

- i. Payment is made in accordance with a written agreement between a paying entity and the practitioner which sets out the payments to be made and the terms under which they are to be provided.
  - ii. The practitioner must certify that for the initial coverage period (not to exceed one year) the practitioner has a reasonable basis for believing that at least 75% of the practitioner's obstetrical patients either reside in a HPSA (health practitioner shortage area) or MUA (medically underserved area) or be part of a MUP (medically underserved population), as defined and thereafter, for each additional coverage period (not to exceed one year) at least 75% of the obstetrical patients treated under the prior coverage period must have met these requirements.
  - iii. There must be no requirement that the practitioner make referrals to, or otherwise generate business for, the entity as a condition of or receiving the benefits."
  - iv. The practitioner must not be restricted from establishing staff privileges at, referring any service to, or otherwise generating any business for any other entity of his or her own choosing."
  - v. The amount of payment made must not be based on the volume or value of previous or expected referrals or business otherwise generated for the entity by the practitioner for which payment may be made in whole or in part under any federal health care program.
  - vi. The practitioner must treat obstetrical patients who receive medical benefits or assistance under any Federal health care program in a nondiscriminatory manner."
  - vii. The insurance must be a bona fide malpractice insurance policy or program and the premium calculated based on a bona fide assessment of the liability risk covered under insurance. For practitioners who engage in obstetrical practice on a part-time basis, this would include the costs attributable exclusively to the obstetrical portion of the practitioner's malpractice insurance and related exclusively to obstetrical services provided in a primary care HPSA.
- b. In a preamble to this safe harbor regulation, DHHS stated that, while it was not defining the full scope of a *bona fide* insurance product, "we believe that certification by a qualified actuary that the program is adequate relative to the risk insured would be an indicator of a bona fide insurance program." 64 Fed. Reg. 63547.

- c. This safe harbor is limited to obstetricians, or persons who practice obstetrics on at least a part-time basis. Consequently, the safe harbor, will not be applicable to physicians other than physicians who practice obstetrics.
  - d. Since this only applies to a primary care HPSA, its application is quite limited.
5. OIG Advisory Opinions and Letters. The OIG will issue advisory opinions as to whether the OIG believes that particular arrangements may violate the anti-kickback statute, if the requisite intent to reward referrals is present, and whether the OIG would seek to impose administrative sanctions in connection with the arrangement. There are two OIG advisory opinions and one OIG “informal” letter which address malpractice subsidies, and allow them in particular situations. These authorities provide some guidance as to the manner in which the OIG will evaluate subsidy arrangements.

a. Advisory Opinion 04-11 (September 2, 2004)

In Advisory Opinion 04-11, the OIG approved a hospital’s proposed arrangement to provide subsidies to community-based obstetricians on its medical staff, where the arrangement met all of the requirements of the above referenced safe harbor except that the practice was not in a primary care HPSA.

The obstetricians in question had experienced significant and rapid increases in their insurance premiums (\$36,000 within one year). The hospital attributed at least some of the increase in the premium to the backup services provide by the obstetricians to the hospital and the community, particularly in high risk cases. The obstetricians assist family practitioners and nurse-midwives employed by the hospital with high risk and complicated cases, and one of the obstetricians was available at all times to provide back up obstetrical services at the hospital and an affiliated migrant health clinic. The obstetricians were not practicing in a primary care HPSA, as required under the safe harbor, but the hospital certified that at least 95% of their patients would reside in a HPSA, a MUA or be members of a MUP. The hospital certified that the obstetricians would, absent a subsidy, otherwise likely cease practice in the area with a resulting thirty percent decrease in access to such care.

To preserve access to obstetrical care, the hospital proposed a malpractice subsidy program. Under the plan the hospital would partially subsidize the malpractice coverage over a two year period by paying 50% of the premium increases above base year cost. Subsidies would be capped at \$25,000 annually per physician. The hospital would pay the insurer directly, and the obstetricians would be covered at all their practice sites, not only at the hospital. The subsidy would not vary based on the value of

any previous or expected referrals or business generated. The hospital certified that the subsidized insurance would be a bona fide malpractice insurance policy with the premium calculated based on a bona fide assessment of the liability risk.

The subsidy agreement would be in writing and the physician would agree to continue providing obstetrical services at the hospital and a local migrant health clinic. The physicians would be required to remain members in good standing of the hospital medical staff, abide by all rules and regulations, and would not be required to make referrals to the hospital or limit their hospital practice to the subsidizing hospital. The arrangement met all of the requirements of the safe harbor discussed above except one: the obstetricians did not practice in a primary care HPSA, although they practiced in a community with three other HPSA designations.

The OIG concluded that the failure to meet this one safe harbor requirement did not increase the risk of fraud, and found the subsidy arrangement consistent with the intent of the statutory safe harbor: to ensure patient access to needed obstetrical care, especially for indigent populations at especially high risk. The advisory opinion noted that the proposed subsidies would not result in a windfall for the private physicians, who would continue to pay the baseline premium plus half of the increase. The subsidies would be time-limited, and would cover all community practice sites, not only the hospital. Finally the OIG noted that there were substantial community benefits to the arrangement, as the obstetricians would treat an underserved rural and migrant worker population.

In this Advisory Opinion, the OIG reiterated its historical concerns with a Hospital's subsidy of malpractice insurance premiums, but also recognized the importance of ensuring access to care, stating:

The OIG historically has been concerned that a hospital's subsidy of malpractice insurance premiums for potential referral sources, including hospital medical staff, may implicate the anti-kickback statute, because the payments may be used to influence referrals. There is a particular concern where subsidies are offered in a conditional or selective manner that reflects current or anticipated referrals from the subsidized practitioners. At the same time, the OIG has recognized the importance of ensuring access to obstetrical care in underserved areas and for underserved populations by establishing the safe harbor for obstetrical malpractice premium subsidies.

b. Advisory Opinion No. 04-19 (January 6, 2005).

Advisory Opinion No. 04-19 goes well beyond the safe harbor to allow malpractice subsidies to avert retirement of two neurosurgeons, who practiced together. Two weeks before the expiration date of their malpractice insurance policy, the insurance company (the “original carrier”) informed them that it would not renew their coverage for their “claims-made” policy. However, it offered to provide tail insurance to the neurosurgeons at no charge, provided that they retired from medical practice. If the physicians continued practicing, the original carrier would charge a fee for the tail coverage. Thus, if they remained in practice, the neurosurgeons would need to obtain insurance to cover claims arising from their ongoing practice as well as additional coverage for claims brought based on prior conduct. The new coverage would cost substantially more than prior coverage. The neurosurgeons informed the hospital that they would both retire immediately unless the Hospital subsidized their malpractice insurance expenses.

The Hospital served as a hub for neurosurgical services in the county and neighboring counties and depended on the neurosurgeons to ensure access to neurosurgical services, especially for emergency care. The next closest hospital providing such services was 45 miles away. Neurosurgeons provided a substantial amount of care to Medicaid and indigent patients. The hospital had for two years tried to recruit a new neurosurgeon without success (although one was recruited after the subsidy arrangement was completed).

In light of these considerations, the hospital entered into an arrangement pursuant to which it agreed to subsidize: (i) the entire cost of tail coverage from the original carrier; (ii) a portion of the increased premiums for claims-made coverage from the physician’s new carrier; and (iii) all or part of the cost of tail coverage from the new carrier at the end of the second year of the agreement, if required, up to a set amount. Under this arrangement, the physicians still incurred increased out-of-pocket expenses for their insurance. Specifically, the hospital’s payments equaled the entire cost of the tail coverage from the old carrier plus 75% of the difference between the neurosurgeons new and prior premium expenses. Given the time constraints, the hospital paid the first year’s subsidy to the physicians. The arrangement provided for payments by the hospital in the second year if the community need persisted and the physicians again faced significant increases. There were no significant increases in the second year; as such, the hospital did not provide a subsidy for the second year of claims-made coverage.

The hospital certified that the amount of payment did not and would not take into account any referrals or business generation by the neurosurgeons. The neurosurgeons were not required to refer patients that generate business to the hospital, and were permitted to furnish services at sites other than the hospital which would still be covered by the subsidized malpractice insurance. In return, the neurosurgeons agreed to comply with all requirements by maintaining membership on the hospital's medical staff, maintaining a full-time practice in neurosurgery in the community, take neurosurgical call for the emergency department, participate in assigned hospital committees, continue to provide care to Medicare beneficiaries, provide at least as much Medicaid and social indigent care as when they entered into the arrangement and cooperate with the hospital's efforts to recruit an additional neurosurgeon(s).

The OIG, noting that it was mindful of the concerns regarding obtaining malpractice insurance, concluded that the facts and circumstances of this arrangement, in combination, "adequately reduced the risk that the [support from the hospital] could be an improper payment for referrals or the generation of Federal health care program business." The reasons for this conclusion were: (1) the arrangement was a temporary and urgent measure to prevent a gap in the local availability of neurosurgical services that would have resulted if the only neurosurgeons in the area had retired (this was a measure to solve an immediate need, limited to two years, and the hospital's support was conditioned on continued community need and premium increases); (2) the arrangement was structured to prevent a financial windfall for the neurosurgeons as they would incur any malpractice premium expenses during the two years that exceeded their expenses in the year prior to the arrangement; (3) the risk of undue benefit was further reduced because the neurosurgeons were required to perform various services as consideration for the support, including, for example, call coverage, maintaining full-time practice, service on hospital committees and furnishing Medicaid and indigent care services; and (4) the fact that the insurance covered services at sites other than the hospital minimized the risk that the support might be connected to referrals (noting that while the physicians were required to be on the hospital's medical staff, there was no requirement that they refer patients or general business, and the hospital certified that the support was not, and would not become it based on the volume or value of referrals or business generated).

In approving this arrangement, the OIG again noted its historical concern with the subsidy of malpractice premiums for referral sources, but also stated its recognition of the possible effects of the increasing cost of malpractice insurance:

*"The OIG is aware that in some geographic areas, some physicians are experiencing dramatic*

*malpractice liability premium increase, insurer withdrawals from certain markets, or sudden terminations of coverage for reasons unrelated to claims history. The OIG recognizes the potential impact of these developments on patient's access to medically necessary care."*

OIG Adv. Op. No. 04-19, p. 7.

c. January 15, 2003 Advice Letter

In this letter the OIG addressed certain proposed arrangements which the requesting party wanted to implement to provide temporary assistance in obtaining professional liability insurance to physicians on its medical staffs in West Virginia, Nevada, Florida and Texas. The requesting party believed that these arrangements needed to be implemented immediately to forestall disruption in the provision of medical services in these states. The OIG did not specifically approve the proposed arrangement as an Advisory Opinion had not been requested. However, the OIG noted a number of safeguards: (1) the arrangements will be provided on an interim basis for a fixed period in states experiencing "severe access or affordability problems," although they could be extended if there was a continuing disruption in a state's malpractice insurance market; (2) only current active medical staff or physicians joining the medical staff who are new to the locality or had been in practice for less than one year would be eligible; (3) the criteria for receiving assistance was not related to the volume or value of referrals or business generated; (4) each physician would pay at least as much he/she currently paid for malpractice insurance; (5) participating physicians will be required to perform services and give up certain litigation rights, which were represented to be equal to the fair market value of the insurance assistance; and (6) the insurance assistance will be available regardless of the location at which the physicians provided services, including at other hospitals.

6. Taking these three OIG Advisories together, the following may be said about the position of the OIG as to subsidization of malpractice insurance by hospitals for physicians:
  - a. The OIG continues to express concern that malpractice premium subsidies paid to, or on behalf of, potential referral sources may be suspect under the anti-kickback statute.
  - b. Nevertheless the OIG has recognized that, in certain locations, there may be a disruption in the medical malpractice liability insurance market and appreciates the potential serious effects on Federal health care

beneficiaries' access to, and on the quality of, medical care if physicians curtail or cease practicing as a result of increased costs or decreased access.

- c. The OIG has been willing to approve arrangements, i.e. not impose administrative sanctions, where safeguards minimize the risk of fraud and abuse, in particular, the inducement of referrals or expected generation of business.
  - d. Although the safe harbor applies only to obstetrical services, the OIG has been willing to consider approving, or at least not disapproving in the case of the informal letter, hospital subsidies with respect to physicians practicing in other areas.
  - e. The situations where the OIG has looked with some favor on hospital subsidies involved situations where serious access problems have been demonstrated, or at least seriously alleged, to be likely (indeed in one case imminent) if insurance was not subsidized and the subsidy was only intended to exist for a defined period of time.
  - f. There was no financial windfall to the physicians; they continued to pay more than they would have even without the subsidy.
  - g. Physicians were not required to make referrals or generate business for the hospital.
  - h. The level of support was not based on the volume or value of referrals or business generated.
  - i. The insurance would cover the physicians regardless of the site where they performed services. The physicians were required to perform services for the hospital.
7. Note that all the above authorities relate only to the issue of whether the subsidies are legal under the anti-kickback law. Stark and IRS analysis is separate.

**B. Stark**

The Stark law prohibits a physician from making referrals to an entity for the furnishing of “designated health services” (including hospital services) for which the Medicare program may otherwise pay, if the physician has a financial relationship with that entity, unless one of the applicable exceptions apply.. It also prohibits the entity, to which the referrals are made, including hospitals, from presenting a claim for payment, or billing others, for designated health services furnished pursuant to a prohibited referral. The Stark law provides as follows:

§ 1395nn. Limitation on certain physician referrals.

(a) Prohibition of certain referrals.

(1) In general. Except as provided in subsection (b), if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this title [42 USCS §§ 1395 et seq.], and

(B) the entity may not present or cause to be presented a claim under this title [42 USCS §§ 1395 et seq.] or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

(2) Financial relationship specified. For purposes of this section, a financial relationship of a physician (or an immediate family member of such physician) with an entity specified in this paragraph is—

(A) except as provided in subsections (c) and (d), an ownership or investment interest in the entity, or

(B) except as provided in subsection (e), a compensation arrangement (as defined in subsection (h)(1)) between the physician (or an immediate family member of such physician) and the entity.

An ownership or investment interest described in subparagraph (A) may be through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.

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42 U.S.C. § 1395nn(a).

1. The Stark statute differs from the anti-kickback statute in several respects. First, the Stark statute is not a criminal law. While the sanctions can be severe, there are no criminal penalties attached to the Stark law. Second, the Stark statute is not an intent-based statute. If a referral is made which is contrary to the statute, unless an exception applies, it is prohibited, regardless of the intent of the party making the referral or the party receiving the referral.
2. The first question in analyzing a situation under the Stark statute is whether a physician has a “financial relationship” with the entity to which referrals are

made. A “financial relationship” can exist either where the physician has an “ownership or investment interest in the entity,” or there exists a “compensation arrangement [as defined] between the physician (or an immediate family member of such physician) and the entity.” 42 U.S.C. § 1395nn(a)(2). The DHHS has promulgated regulations further defining when a financial relationship exists. See 42 C.F.R. § 411.354. A financial relationship means either “[a] direct or indirect ownership or investment interest [as defined] in any entity that furnishes DHS [designated health services]” or “[a] direct or indirect compensation arrangement [as defined] with an entity that furnishes DHS.” Id. § 411.354(a)(1)(i)(ii).

3. The regulations define when a direct or indirect financial relationship exists. “A direct financial relationship exists if remuneration passes between the referring physician (or a member of his or his immediate family) and the entity furnishing DHS without any intervening persons or entities.” 42 C.F.R. § 411.354(a)(2). For example, a direct financial relationship would exist if a hospital were to make payments directly to physicians who then used those payments to pay for malpractice insurance premiums.<sup>1</sup> As noted, a financial interest may involve either an “ownership or investment interest” or a “compensation arrangement.” 42 U.S.C. § 1395nn(2); 42 C.F.R. § 411.354(a). An ownership or investment interest “may be through equity, debt or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service.” 42 U.S.C. § 1395nn(2). This would include, but is not limited to, “stock, stock options [other than certain stock options], partnership shares, limited liability company memberships, as well as loans, bonds, or other financial instruments that are secured with an entity’s property or revenue or a portion of that property or revenue.” 42 C.F.R. § 411.354(b)(1).
4. The term “compensation arrangement” is defined both in the Stark statute and in CMS regulations. A compensation arrangement “means any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity” other than certain remuneration excepted by the statute. 42 U.S.C. § 1395nn(h)(1)(A).<sup>2</sup> The term “remuneration” in the statute is defined broadly as it is in the anti-kickback statute to include “any remuneration, directly or indirectly, overtly or covertly, in cash or in kind.” Id. § (h)(1)(B). See 42 C.F.R. § 411.354(c).
5. Exceptions. There are two key Stark exceptions to consider in reference to malpractice subsidies.

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<sup>1</sup> In Advisory Opinion 04-11 discussed above, the hospital made the payment on behalf of the physicians directly to the insurance company. In OIG Opinion 04-16, given the time constraints under which the arrangement was implemented, the hospital paid the first year’s premium support to the physicians upon documented proof of their expenditures. This difference in the method of payment did not, in either of these cases, figure significantly into the OIG’s analysis. However, it should be remembered that the OIG was concerned with the anti-kickback statute, not the Stark law.

<sup>2</sup> The excepted remuneration provision of the statute is not applicable. See 42 U.S.C. § 1395nn(h)(1)(C).

- a. One is the exception for “obstetrical malpractice insurance subsidies.” 42 C.F.R. § 411.357(r). The requirements for this exception, which would apply only to obstetricians, are the same as the requirements for the obstetrical malpractice insurance subsidy exception under the anti-kickback law (discussed above).
- b. The second is the exception for “[f]air market value compensation.” 42 C.F.R. § 411.357(l). Fair market value compensation resulting from an arrangement between an entity and a physician for the provision of items or services by the physician to the entity does not constitute a “financial relationship” for purposes of the Stark law if the following conditions are met:
  - i. The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in the agreement.
  - ii. The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement made for less than 1 year may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.
  - iii. The writing specifies the compensation that will be provided under the arrangement. The compensation must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of referrals or other business generated by the referring physician.
  - iv. The arrangement would be commercially reasonable (taking into account the nature and scope of the transaction) and further the legitimate business purposes of the parties.
  - v. It does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.
  - vi. The services to be performed under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates a State or Federal law.

Id.

If a hospital wanted to subsidize a portion of the professional liability premium paid to the captive by a physician, it is possible that the fair market value compensation exception may have some applicability if the six requirements set forth above are met. For example, the Hospital might, following the above Advisory Opinion 4-19,<sup>3</sup> require that the physicians maintain membership on the Hospital's medical staff, maintain a full-time practice in their specialty in the community, take call for the emergency department, participate in assigned hospital committees, continue to provide care to Medicare beneficiaries, provide at least as much Medicaid and social indigent care as when they entered into the arrangement and cooperate with the hospital's efforts to recruit additional physicians.

**C. Federal Tax – Exemption Considerations.**

If the health care organization is a 501(c)(3) tax-exempt organization, it must be organized and operated exclusively for charitable and other exempt purposes. IRC sec. 501 (c)(3). The term "charitable" includes the promotion of health. Treas. Reg. sec. 1,501(c)(3)-1(d)(2). The Internal Revenue Code and regulations require that the net earnings of an exempt organization not inure to the benefit of persons having a private interest in its activities, and that it serve a public rather than a private interest. All activities of an exempt organization must be carried out within these guidelines.

1. If a tax-exempt hospital participating in a captive insurance program with physicians pays premiums or contributes capital that is disproportionately greater than the hospital's actual risk the contribution may be viewed as a distribution of exempt assets to individuals in violation of the private inurement prohibition.
2. No part of the net earnings of a federally tax-exempt organization may inure to the benefit of any private shareholder or individual. Inurement will exist when an exempt organization is paying more than reasonable compensation, or is not receiving fair value for payments made. A hospital's payment of the malpractice insurance premium of a physician it does not employ, therefore, could be construed as private inurement if the hospital does not receive fair value in return.
3. There is a recent private letter ruling approving malpractice subsidies by a tax exempt entity in certain circumstances. In a private letter ruling issued in August 2003, the Internal Revenue Service addressed the issue of whether a private foundation should be allowed to subsidize the malpractice premiums of a taxable subsidiary writing professional liability insurance. PLR 200347017 (August 29, 2003) As in the case of OIG Advisory Opinions, a private letter ruling is applicable only to the organization which has requested the ruling, and it may not be used or cited as precedent. However, private letter rulings do provide some

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<sup>3</sup> The Advisory Opinion is cited here for illustrative purposes only as it pertains directly only to the anti-kickback law and not the Stark law.

guidance as to how the Internal Revenue Service will evaluate a particular set of facts.

In PLR 200347017, a 501(c)(3) private foundation that was created to benefit the health care system in eight counties of a state experiencing a malpractice insurance crisis was allowed to create a reinsurance company as a taxable subsidiary for the purpose of writing professional liability insurance. A majority of the board of directors of the taxable subsidiary were independent, and the organization and governance of the subsidiary were separate from that of the foundation. The IRS allowed the foundation to fund the subsidiary's activities, stating that the benefit to the physicians was incidental to the attainment of the exempt purpose of promoting health of the community. Based upon this private letter ruling, if a hospital's corporate purposes include the promotion of health in the community and if the hospital's captive insurance company has the characteristics described in the private letter ruling, an argument could be made that a grant from the hospital to the captive to support its activities (and reduce premium costs to doctors) would not jeopardize the hospital's tax exemption. However, this argument would probably be weakened to the extent only the premium costs of doctors strategically important to the hospital are reduced.

4. If a physician who met the definition of “disqualified person” (i.e. an insider) were to receive a subsidy which was deemed to violate the Internal Revenue Code, there would be the possibility that the Internal Revenue Service could impose a so-called Intermediate Sanction against the directors, officers or managers involved as well as against the physician. To seek to avoid this sanction, there is a so-called safe harbor provision. Under the safe harbor provision, compensation is presumed to be reasonable, and a property transfer is presumed to be at fair market value if:
  - a. the compensation arrangement or terms of transfer are approved, in advance, by an authorized body of the exempt organization, composed entirely of individuals without a conflict of interest,
  - b. the board or committee obtained and relied upon appropriate data as to comparability in making its determination, and
  - c. the board or committee adequately documented the basis for its determination, concurrently with making the decision.

The disqualified person/organization manager normally has the burden of proving that the compensation was reasonable. However, if the three criteria above are met, the burden of proof shifts to the IRS and the IRS must prove that the compensation was unreasonable.

### **III. INSURING PHYSICIANS THROUGH A CAPTIVE**

#### **A. Anti-kickback**

1. When physicians are insured by a captive insurance company sponsored by a hospital or other health care organization many of the same issues may arise as with direct payment of physicians' malpractice insurance premiums.
2. As noted above, the wording of the anti-kickback statute, in particular the definition of remuneration, is broad.
  - a. The offering of a premium at below market value rates could well be viewed by the OIG as remuneration.
  - b. For this purpose, "market value" should mean "actuarially sound". In other words, the captive format produces savings for the physician whether or not the rates are being subsidized. Therefore, if the captive physician rates are not being subsidized by the hospital but rather are deemed actuarially sound without such subsidy, this should be viewed as the equivalent of market value.
  - c. Therefore, it would appear that if the rates are actuarially sound, or if the subsidy was permitted under the above authorities, the anti-kickback law would not be violated.

#### **B. Stark**

1. A captive normally does not provide medical services, but Stark would potentially apply as an indirect compensation arrangement. The CMS regulations define the elements of an indirect compensation arrangement. There are three elements to such an arrangement. 42 C.F.R. § 411.354(c)(2). The definition is as follows:

(2) Indirect compensation arrangement. An indirect compensation arrangement exists if –

(i) Between the referring physician (or a member of his or her immediate family) and the entity furnishing DHS there exists an unbroken chain of any number (but not fewer than one of persons or entities that have financial relationships (as defined in paragraph (a) of this section) between them (that is, each link in the chain has either an ownership or investment interest or a compensation arrangement with the preceding link);

(ii) The referring physician (or immediate family member) receives aggregate compensation from the person or entity in the chain with which the physician (or immediate family member) has a direct financial relationship that varies with, or otherwise

reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS, regardless of whether the individual unit of compensation satisfies the special rules on unit-based compensation under § 411.354(d)(2) or (d)(3). If the financial relationship between the physician (or immediate family member) and the person or entity in the chain with which the referring physician (or immediate family member) has a direct financial relationship is an ownership or investment interest, the determination whether the aggregate compensation varied with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS will be measured by the non-ownership or non-investment interest closest to the referring physician (or immediate family member). (For example, if a referring physician has an ownership interest in company A, which owns company B, which has a compensation arrangement with Company C, which has a compensation arrangement with entity D that furnishes DHS, we would look to the aggregate compensation between company B and company C for purposes of this paragraph (c)(2)(ii)); and

(iii) The entity furnishing DHS has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the referring physician (or immediate family member) receives aggregate compensation that varies with, or otherwise reflects, the volume or value of referrals or other business generated by the referring physician for the entity furnishing the DHS.

3. A captive insurance program can be seen to give rise to a chain of persons or entities that have financial relationships between them. For example, a hospital's direct or indirect investment or ownership interest in the captive is one element of the chain. The second element of the chain would be the compensation arrangement between the captive and its insured physicians.

The second element of the indirect compensation arrangement requires that the referring physician receive "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 the referrals of other business generated by the referring physician for the entity furnishing the DHS . . ." *Id.* § (c)(2)(ii) (emphasis added). Thus, if a physician's premium (or any subsidy) does not vary in any way related to the physician's referrals to the Hospital or other business generated for the Hospital, there would be no indirect compensation arrangement under Stark.

One problem is that a captive insurer which insures both physicians and a hospital normally is seeking to insure physicians who practice at the hospital in a

substantial way, so that when there are suits, the hospital insured rather than some other hospital, and the physician can both be provided with a common defense, thereby achieving the desired cost savings. Therefore, it is possible the government might argue that the premiums should be viewed as giving rise to an indirect compensation relationship between a physician and a hospital for Stark law purposes, because eligibility for the insurance coverage might be deemed to contemplate that there is at least some level of business generated for the Hospital. If this is the case, it may be necessary to consider the exception for indirect compensation arrangements which will be discussed below. See 42 C.F.R. § 411.357(p).

4. If the relationship between the Hospital and the physicians is determined to be an indirect compensation arrangement, as discussed above, the exception for indirect compensation arrangements should be considered. See 42 C.F.R. § 411.357(p). This exception states as follows:

*“(1) The compensation received by the referring physician (or immediate family member) described in § 411.354(c)(2)(ii) is fair market value for services and items actually provided and not determined in any manner that takes into account the value or volume of referrals or other business generated by the referring physician for the entity furnishing DHS.*

*(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set forth in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a bona fide employment relationship between an employer and an employee, in which case the arrangement need not be set out in a written contract, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.*

*(3) The compensation arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.”*

Id.

For purposes of the indirect compensation exception, the compensation link in the chain closest to the physician, here the relationship between the physician and the captive must meet these criteria. To the extent that a favorable premium is used as compensation, it will not trigger a compliance issue if: the premium reflects actuarial determined fair market value; is not determined in a manner that takes

into account the volume or value of a physician's referrals or other business generated for the Hospital; it is set out in writing; and does not violate the anti-kickback statute.

Here actuarial reports may be helpful. If an actuary determines that the physicians are paying fair market value for their insurance, then the exception would apply.

**C. Tax Exemption Considerations**

A Hospital's ownership of a captive insurance company which provides medical malpractice insurance to private, non-employed physicians, raises two issues which must be examined in light of the Hospital's tax exempt status: whether any of the net earnings of the Hospital inure to the benefit of a person having a private interest in its activities; and, whether the operation of the exempt organization, i.e. the Hospital, serves any private interests other than incidentally.

- a. In the first instance, a Hospital may argue that the activities of the captive insurance company should not be attributed to the Hospital. However, there is a possibility that the activities of the captive might be attributed to the Hospital or that the Hospital's payment of excessive premium and capitalization could be seen as subsidization of physicians.
- b. If the Hospital is not subsidizing the captive, then this should not be a problem. If it is, then the issue of whether there was a tax exemption problem would be the same as for a direct subsidy, as discussed above.

**D. Medicare Reimbursement Issues.**

1. The Medicare Provider Reimbursement Manual (PRM) allows for a number of alternatives for a hospital to obtain professional liability insurance coverage, including commercial insurance, self insurance, a combination of self and commercial insurance, and insurance through a limited purpose insurance company, i.e., a captive insurance company.
2. Premiums paid to a captive insurance company are recognized as allowable costs if all of the conditions prescribed in the PRM are met.
  - a. Regular premiums paid to a captive insurance company for provider malpractice and comprehensive general liability coverage in conjunction with malpractice coverage are allowable costs if they are not in excess of the cost of available comparable commercial insurance and meet Medicare's reasonable cost requirements.
  - b. Supplemental premiums which are assessed by the captive insurance company to build reserves against contemplated losses are also allowable

costs if, when added to the regular premium, the total premium cost does not exceed a commercial insurance premium for comparable coverage.

- c. Initial or subsequent capital payments, as distinguished from supplemental premiums, are not allowable under Medicare.
  - d. If comparable insurance premiums are not available, the captive insurance company may be required to obtain an evaluation of the adequacy and reasonableness of its insurance premiums by an independent actuary, commercial insurance company or broker.
  - e. Where both Medicare and non-Medicare providers participate and pay premiums, the premiums must be determined so that Medicare providers do not bear premium costs of non-Medicare providers and vice versa.
3. The captive insurance company also must have adequate claims management and risk management programs.
4. If a provider or a group of providers is related to the insurer through ownership or control, as defined by Medicare, additional provisions apply, including:
- a. The captive must be established in and meet the appropriate insurance laws of the United States, the District of Columbia, or a foreign government, if it is formed offshore;
  - b. The excess of the actuarial determined loss reserves and related operating expenses over the actual losses and related operating expenses and gains and losses from investments must be taken into account in establishing reasonable premium levels which do not reflect a profit factor.
  - c. Upon termination from the Medicare program, a professional evaluation of the adequacy of premium reserves as of the date of termination must be obtained and reserves that are deemed excessive must be offset against allowable costs in the provider's final cost report.
5. Investments
- a. Investments by a related offshore captive insurance company are limited to low risk investments in United States dollars such as bonds and notes issued by the United States government, debt securities issued by United States corporations or governmental entities in the United States, certain debt securities of foreign subsidiaries of United States corporations, certificates of deposit in United States banks or their foreign subsidiaries and foreign banks, and certain other investments rated in the top two or three classifications by United States recognized security rating

organizations, depending on when the investment is made. Other limitations are also set forth in the PRM.

- b. Captives are required to annually submit to a designated intermediary a certified statement from an independent certified public accountant or actuary attesting to compliance or noncompliance with these requirements.
  - c. These investments cannot be used as collateral for loans obtained by the captive or parties related to the captive nor may investments be made in a related organization.
6. Loans or any transfer of funds by the insurance company to policyholders, owners of providers or parties related to them are prohibited.