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I. INTRODUCTION

Section 1128B(b) of the Social Security Act,[1] better known as the Medicare and Medicaid anti-kickback statute or fraud and abuse statute, broadly prohibits the knowing and willful offer, payment, solicitation, or receipt of remuneration in return for the referral of an individual for any item or service covered under the Medicare or Medicaid programs.[2] This statutory language is so broad that the anti-kickback statute could easily be interpreted to prohibit a wide range of traditionally accepted business arrangements involving healthcare providers.

The Office of the Inspector General ("OIG")[3] of the Department of Health and Human Services has been active in urging the courts to adopt an expansive interpretation of the anti-kickback statute. It appears that the courts have accommodated the OIG. The federal case law broadly interprets the statute to prohibit any exchange of remuneration where even one purpose of the

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1. 42 U.S.C.A. § 1320a-7b(b) (West 1991).

2. *Id.* The Department of Health and Human Services typically uses the more generic term "State Health Care Program" when referring to Medicaid and other related state healthcare programs. For purposes of this article, the term "Medicaid" will be used to refer to all state healthcare programs.

3. The OIG operates as an independent unit within the Department of Health and Human Services, responsible for "conducting investigations into suspected fraud or abuse, performing audits and inspections of Departmental programs as well as data collection and analysis, special studies, and other functions designed to meet its overall mission." 3 Medicare & Medicaid Guide (CCH) ¶ 13,915, at 5,635.

remuneration is to induce the referral of Medicare or Medicaid recipients.

The OIG's efforts to broaden the reach of the anti-kickback statute are continuing. Its most recent effort concentrates on expanding the class of potential "referrers" to include hospitals and similar health institutions. The OIG issued a management advisory report,[4] which suggests that certain common business arrangements between hospitals and hospital-based physicians[5] violate the anti-kickback statute. Specifically, the OIG has stated that any arrangement that requires hospital-based physicians to "split portions of their income with hospitals" or pay "far in excess of the fair market value of services provided by the hospital" may violate the statute and come under fraud and abuse scrutiny.[6]

The hospital industry, through the American Hospital Association ("AHA"), has taken issue with the position of the OIG.[7] The AHA contends that physicians, not hospitals, make referrals for health services; therefore, the anti-kickback statute does not apply to arrangements between hospitals and hospital-based physicians.[8]

This article focuses on the statutory prohibition against remuneration in return for referrals as it applies to the relationship between hospitals and hospital-based physicians. It will analyze the

4. Office of the Inspector General, Department of Health and Human Services, Financial Arrangements Between Hospitals and Hospital-Based Physicians, Medicare & Medicaid Guide (CCH) Transfer Binder 1992-1 ¶ 39,669 (Oct., 1991) [hereinafter OIG Management Advisory Report]. The OIG sent an original management advisory report to the Department of Health and Human Services, Health Care Financing Authority ("HCFA") on January 31, 1991 (found at Medicare & Medicaid Guide (CCH) Transfer Binder 1991 ¶ 39,044). On March 11, 1991, Paul Rettig, Executive Vice-President of the American Hospital Association, responded to the management advisory report. The report and Mr. Rettig's response were reviewed by HCFA, which issued comments on May 2, 1991. Mr. Rettig's letter and the HCFA comments can be found at *Medicare Safe Harbor Regulations on Fraud & Abuse*, ABA FORUM ON HEALTH LAW, Section E (Sept., 1991). In response to these comments as well as those received from the College of American Pathologists, the OIG issued a revised report in October, 1991.

5. The term "hospital-based physicians" is typically used to refer to radiologists, anesthesiologists, pathologists, emergency medicine physicians, and, in some cases, teaching physicians.

6. OIG Management Advisory Report, *supra* note 4, at 28,416. These arrangements have been called "reverse kickbacks" since the application of the anti-kickback statute to payments from physicians to hospitals is somewhat atypical. The more typical application of the statute would prohibit hospitals from paying physicians for referrals. *See* Linda Perry, *Virginia Legal Battle Highlights Unrest Between Hospitals, Physicians*, MOD. HEALTHCARE, Sept. 17, 1990, at 36.

7. March 11, 1991, letter from Paul Rettig, *supra* note 4. The American College of Radiology and the American College of Pathology both issued position papers that strongly support the Inspector General's position on this issue.

8. *Id.* at p. 2. *See also OIG Memo Causes Concern in Health Care Circles*, HOSPITAL, May 20, 1991, at 66.

anti-kickback statute and the positions of both the OIG and the AHA regarding this controversy. Specifically, this article provides a general background of the statute, reviews the elements of a violation of the statute and their application to arrangements between hospitals and hospital-based physicians, discusses the application of the "safe harbors" to business arrangements between hospitals and hospital-based physicians, reviews relevant litigation involving allegedly abusive business arrangements between hospitals and hospital-based physicians, and analyzes several implications of applying the anti-kickback statute to business arrangements between hospitals and hospital-based physicians.

II. BACKGROUND

A. The Economics of Referral Power

One of the many unique characteristics of the healthcare industry lies in the fact that a third-party, not a consumer, often makes the purchase decision. For example, if a physician determines that a patient needs a diagnostic imaging service, the patient's attending physician usually refers the patient to a radiologist for the diagnostic study. Similarly, if a patient needs a laboratory analysis of a tissue sample, the patient's physician often arranges for a pathologist to conduct the study. In most cases, the patient follows his or her "doctor's order" and complies with the "recommended" treatment course. Hence, it is the physician, not the consumer, who to a large extent controls utilization of healthcare services and healthcare decision making.

A byproduct of this referral-driven approach to the purchase of medical services is the temptation presented to referring physicians to profit from their referral power. There are a number of ways in which a physician can profit, either directly or indirectly, from this referral source power. At one extreme, a referring provider might demand some type of direct payment, based on the volume of business referred, from the provider who benefits from the referrals, the classic "kickback." A less direct way for providers to reap the benefit of their referral power is through ownership of an equity interest in an entity to which the physician is in a position to direct referrals.[9] The more patients the provider directs to the entity, the

9. A common example of this type of arrangement is a free-standing diagnostic imaging center in which the principal shareholder (or general partner) sells shares (or limited partnership interests) to physicians who are in a position to generate referrals to the center.

more revenue the entity generates and the greater the referring provider's return on investment.

Arrangements that enable providers to be compensated for their referral power can cause harm in three ways. First, these types of arrangements can result in the provision of unnecessary medical services, referred to as "overutilization."[10] Overutilization results in an increase in cost to both the patient and the patient's health insurance carrier by driving up the total cost of the patient's care. In some cases, overutilization can also have a detrimental medical effect on the patient's health.[11]

Second, these types of arrangements can increase the cost of health care by adding an additional layer of "profit" to the cost of the item or service. Even where utilization is appropriate, compensating providers for referrals can still increase the cost per service if the physician receiving the referral "marks-up" the price of the service to cover the cost of the referral payment. Like overutilization, these types of referral payments increase the cost to the patient and the patient's health insurance carrier.[12]

Finally, these types of arrangements can unnecessarily restrict the patient's freedom of choice. In situations where the referrer has a financial incentive to refer to a particular provider, the patient may not be given a choice. Absent a referral incentive, the physician might be more inclined to present the patient with a list of options or at least learn of any patient preferences.[13]

The payment of compensation in return for referrals can have a substantial effect on the federal government since the government pays for a significant portion of the healthcare services provided in the United States. Payments by the federal government for healthcare services are made primarily through the Medicare and Medicaid programs.[14] Any arrangement that increases the cost of

10. OIG Management Advisory Report, *supra* note 4, at 28,416.

11. *Id.* at 28,416. McCarty Thornton, *The Medicare/Medicaid Anti-Kickback Statute: An Enforcement Perspective, in* 470 A.L.I.-A.B.A. COURSE OF STUDY, at 111 (1989) (discussing, *inter alia*, the rationale behind the existence of the Medicare and Medicaid anti-kickback statute).

12. OIG Management Advisory Report, *supra* note 4, at 28,416 to 28,417.

13. Thornton, *supra* note 11.

14. The Medicare program provides health insurance primarily to individuals who are age 65 and older and who are entitled to retirement benefits under either the Social Security or Railroad Retirement Acts. MARGARET GREENFIELD, MEDICARE AND MEDICAID: THE 1965 AND 1967 SOCIAL SECURITY AMENDMENTS 2 (1968). The Medicaid program provides health insurance coverage to individuals based on their financial status. Medicaid is funded and administered jointly through a cooperative effort between the federal and state governments. *Id.* at 105-125.

providing services to Medicare and Medicaid beneficiaries increases the federal government's total healthcare cost.

B. The Special Relationship Between Hospitals and Hospital-Based Physicians

Unlike primary care and attending physicians, hospital-based physicians typically are not in a position to refer patients to other providers of healthcare services. More commonly, hospital-based physicians, such as radiologists, anesthesiologists, and pathologists, are the recipients of referrals from other physicians. Often, a hospital selects only one group of radiologists, one group of pathologists, and one group of anesthesiologists to provide services at a given facility, and these physicians will receive all of the referrals for services to be provided at the hospital. Hence, by selecting a group of hospital-based physicians that will be the recipients of the hospital's business, the hospital indirectly controls the flow of certain business.

Hospitals and hospital-based physicians frequently enter into contractual relationships under which the hospital-based physicians agree to provide services to the hospital and the hospital's patients.[15] Often these arrangements are in the form of exclusive contracts. While such contractual arrangements, by themselves, do not violate the anti-kickback statute, fraud and abuse questions can arise whenever a business arrangement results in any form of payment that does not reflect fair market value flowing between the physicians and the hospital.[16] For example, a requirement that hospital-based physicians purchase management and billing services from the hospital may be suspect under the anti-kickback statute. Similarly, contract provisions under which the physicians agree to rent space or equipment from the hospital could be suspect. A hospital might also request or require the physicians to make payments that are unrelated to any services, equipment, or facilities provided by the hospital, such as "donations" to charita-

15. These arrangements are frequently made through contracts that give the hospital-based physicians an exclusive franchise to provide services within the hospital, some of which provide for an exclusive right to use the hospital's equipment. These types of relationships will be referred to throughout this article as business arrangements between hospitals and hospital-based physicians. The term "business arrangements" as used in this article does not include joint ventures between hospitals and hospital-based physicians in outpatient facilities.

16. *See* OIG Management Advisory Report, *supra* note 4, at 28,416 to 28,417 (OIG findings regarding the types of suspect business relationships that may exist between hospitals and hospital-based physicians).

ble foundations operated by the hospital.[17] These types of payments that would, in essence, constitute a franchise fee have been specifically condemned by the OIG.

C. *Development of the Anti-Kickback Statute and Regulations*

The anti-kickback statute, originally enacted in 1972, represents an attempt by Congress to curb abusive referral arrangements of the type discussed above. The original statute established criminal sanctions for the solicitation, receipt, offer, or payment of kickbacks, bribes, or rebates in return for referrals.[18] In 1977, the scope of the statute was broadened to prohibit not only kickbacks and bribes, but any remuneration offered, paid, solicited, or received in return for referrals.[19] Despite the broad scope of the anti-kickback statute after the 1977 amendments, there was very little enforcement action in the ten years following the amendments.[20]

In 1987, Congress enacted three additional amendments to the fraud and abuse provisions. First, Congress gave the Department of Health and Human Services ("DHHS"), through the OIG, the ability to exclude providers from participation in the Medicare and Medicaid programs for violation of the anti-kickback law.[21] Second, Congress gave the OIG the ability to impose civil penalties for violations of the anti-kickback statute.[22] Finally, Congress instructed the DHHS to publish regulations defining business arrangements that would be protected from criminal prosecution or civil sanctions under the broad anti-kickback statute.[23]

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17. *Id.* at 28,415; *see* Perry, *supra* note 6, at 34-36.

18. Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972).

19. Medicare and Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, § 4, 91 Stat. 1175, 1179 (1977).

20. SANFORD V. TEPLITZKY & EUGENE TILLMAN, DEVELOPMENT OF THE ANTI-KICKBACK PROVISIONS vii (1989) (attributing the lack of enforcement action to the fact that neither the Health Care Financing Administration nor the OIG believed that they had the authority to interpret a criminal statute).

21. Pub. L. No. 95-142, sec. 2, 101 Stat. 680 (codified as amended at 42 U.S.C.A. § 1320a-7). For many providers, exclusion from participation in the Medicare and Medicaid programs represents financial disaster, since Medicare and Medicaid revenues often account for a significant portion of the provider's total revenues.

22. *Id.* at sec. 3, 101 Stat. 686 (codified as amended at 42 U.S.C.A. § 1320a-7a).

23. *Id.* at sec. 14, 101 Stat. 697. The legislative history of the Medicare and Medicaid Patient and Program Protection Act of 1987 indicates that Congress felt that it was necessary for the DHHS to define protected business arrangements since the breadth of the anti-kickback statue had "created uncertainty among health care providers as to which commercial arrangements are legitimate, and which are proscribed." S. REP. NO. 109, 100th Cong., 1st Sess. 27 (1987), *reprinted in* 1987 U.S.C.C.A.N. 682, 707.

After several years of delay, these regulations were published in the form of 11 "safe harbors." 42 C.F.R. § 1001.952 (1991); *see also* Medicare and State Health Care Pro-

III. THE ELEMENTS OF AN ANTI-KICKBACK VIOLATION AND THEIR APPLICATION TO HOSPITAL-BASED PHYSICIANS

There are three elements necessary to establish a violation of the anti-kickback statute. The business arrangement must (1) involve the offer, payment, solicitation, or receipt of remuneration that (2) is made in return for or to induce the referral of Medicare or Medicaid patients; finally, (3) the offer, payment, solicitation, or receipt of remuneration must be knowing and willful.[24]

A. The "Remuneration" Requirement

As originally enacted, the anti-kickback statute prohibited only those arrangements that involved either a kickback or a bribe. However, in 1977, the statute was expanded to prohibit not only direct kickbacks and bribes, but any remuneration paid or received in return for referrals. The meaning of the term "remuneration" has been broadly interpreted to encompass almost anything of value.

The Third Circuit Court of Appeals decided one of the first cases to address the meaning of "remuneration."[25] A cardiologist, Dr. Greber, appealed his criminal conviction under the anti-kickback statute. In addition to practicing medicine, Greber owned a company that provided diagnostic services to other physicians' patients. Greber's company billed Medicare directly and forwarded an "interpretation fee" to the referring physician for consultation services and for reporting the test results to the patient. Greber argued that in order for the court to find that he had violated the anti-kickback statute, the government had to show that "the only purpose behind the [interpretation] fee was to improperly induce future services . . . ."[26] Greber contended that compensating a physician for services actually rendered could not violate the statute.

The OIG countered that the interpretation fee constitutes "remuneration" in exchange for referrals if one purpose of the payment was to induce a referral. According to the OIG, this is true

grams: Fraud and Abuse; OIG Anti-Kickback Provisions; Rule, 56 Fed. Reg. 35,952 (1991); Michael W. Peregrine et al., *Safe Harbors for Toy Boats: An Analysis and Commentary*, 24 J. HEALTH & HOSP. L. 297 (1991); Deborah Robinson, *Safe Harbors or Empty Harbors?*, HOSP. L. NEWSL., at 1, Dec., 1991.

24. 42 U.S.C.A. § 1320a-7b(b)(1)-(2). The statute prohibits any type of remuneration in return for referrals whether "directly or indirectly, overtly or covertly, in cash or in kind." *Id.*

25. United States v. Greber, 760 F.2d 68 (3d Cir. 1985).

26. *Id.* at 71.

even if the remuneration also compensates a referring physician for services actually performed.

The Third Circuit adopted the OIG's view and upheld Greber's conviction noting that "remuneration" includes not only sums for which no actual service was performed, but also those amounts for which some professional service was rendered. The court concluded that a payment violated the statute if the payment was intended in induce referrals, even if the payment was also intended as compensation for services rendered.[27]

The *Greber* court's interpretation of "remuneration" has been expressly adopted by both the Ninth[28] and First[29] circuits. The *Greber* test has also been expressly adopted in an administrative sanction case heard by the Health and Human Services Departmental Appeals Board, where the Board defined remuneration to include "offering or paying anything of value in any form or manner whatsoever."[30]

In all likelihood, the *Greber* standard will continue to be the test applied by the courts and by administrative law judges, even in the case of hospital-based physicians. In applying the *Greber* test to business arrangements between hospitals and hospital-based physicians, courts will most likely scrutinize the subjective intent of the parties to the arrangement.

B. The "In Return for Referrals" Requirement

To violate the anti-kickback statute, the offer or payment must be made "to induce" referrals while the solicitation or receipt of remuneration must be made "in return for" the referral of Medi-

27. *Id.* at 71-72. The *Greber* court concluded that Congress specifically included the term remuneration in the statute to include situations where some service is actually rendered. It noted that the difference between a kickback and remuneration is that no service is rendered in return for a kickback while some service is actually rendered in return for remuneration. The court explained that "[b]y adding 'remuneration' to the statute in the 1977 amendment, Congress sought to make it clear that even if the transaction was not considered to be a 'kickback' for which no service had been rendered, payment nevertheless violated the [Social Security] Act." *Id.* at 72.

28. United States v. Kats, 871 F.2d 105 (9th Cir. 1989).

29. United States v. Bay State Ambulance & Hosp. Rental Serv., Inc., 874 F.2d 20 (1st Cir. 1989).

30. In re Inspector General v. Hanlester Network, Docket No. C-448, Decision No. 1347 (H.H.S. Departmental Appeals Board, Appellate Division, July 24, 1992), *aff'g in part, rev'g in part* Docket No. C-448, Decision No. CR 181 (H.H.S. Departmental Appeals Board, Civil Remedies Division, Mar. 10, 1992), *on remand from* Docket Nos. C-186 through C-192, No. C-208, & No. C-213, Decision No. 1275 (H.H.S. Departmental Appeals Board, Appellate Division, Sept. 18, 1991). An appeal of the July 24 decision has been filed in federal court.

care or Medicaid patients.[31] These parallel provisions will apply to different conduct depending on whether an individual is offering remuneration to induce a referral or is receiving payment in return for a referral.

Whether hospitals are able to exact payments from hospital-based physicians "in return for referrals" is the principal point of disagreement between the OIG and the hospital industry. The OIG maintains that hospitals are in a position to influence referrals and therefore come within the statute.[32] The AHA argues that other physicians, not hospitals, refer patients; therefore, arrangements between hospitals and hospital-based physicians cannot violate the statute.[33] At the time this article was written, the courts had not yet addressed this conflict.

The AHA also argues that the underlying purpose of the anti-kickback statute, that of avoiding overutilization, is not impacted by the arrangements between hospitals and hospital-based physicians. According to the AHA, there are no studies or reports that document an increase in utilization of services because of arrangements between hospitals and hospital-based physicians. This is in contrast to physician ownership and referral arrangements. The AHA concluded that because increases in utilization have not been demonstrated, the anti-kickback statute is not implicated.[34] However, actual harm to the program or overutilization of services is not required to establish a violation of the anti-kickback statute.[35]

The OIG acknowledges that hospital-based physicians "obtain referrals from other specialists practicing at their hospital."[36] However, the OIG interprets the application of the anti-kickback statute's "in return for referral" requirement to be broader than merely applying to those in a position to make direct referrals. The OIG contends that the statute applies to anyone in a position to "materially influence the flow of Medicare and Medicaid business."[37] The OIG asserts that hospitals "are in such a position . . . since they typically can name [which hospital-based physicians] will be the recipient of the flow of business generated at the hospital."[38]

31. 42 U.S.C.A. § 1320a-7b(b)(1)-(2).
32. *See* OIG Management Advisory Report, *supra* note 4, at 28,415.
33. March 11, 1991, letter from Paul Rettig, *supra* note 4, at 2.
34. *Id.* at 3.
35. Hanlester, Docket No. C-448, Decision No. CR 181, at 25.
36. OIG Management Advisory Report, *supra* note 4, at 28,415.
37. *Id.*
38. *Id.*

To support its conclusion, the OIG relies on *United States v. Bay State Ambulance and Hospital Rental Services, Inc.*[39] In *Bay State*, the First Circuit upheld the anti-kickback criminal conviction of an employee of a city-owned hospital.[40] The employee, Felci, had been instrumental in the hospital's decision to award an ambulance contract to a local company. Before and after the contract was awarded, Felci received two cars and numerous cash payments from the ambulance company. It was the hospital, not Felci, that entered into the contract with the ambulance company. Nevertheless, Felci was convicted based on his ability to influence the hospital in its decision to award the contract to Bay State. The OIG has interpreted *Bay State* to mean the referral requirement of the anti-kickback statute is not limited to those in a position to make direct referrals but rather can be satisfied by those in a position to exert influence over the referral decision.[41]

Additional support for the position of the OIG is found in the *Hanlester* case. In the first administrative sanction decision rendered, the DHHS Departmental Appeals Board broadly defined the phrase "to induce" as "an intent to exercise influence over the reason or judgement of another in an effort to cause the referral of program-related business."[42] This definition leaves ample room for the inducement/in return for requirement to be interpreted to apply to any individual or entity that is in a position to influence the flow of Medicare and Medicaid business.

C. The "Knowing and Willful" Requirement

As originally enacted by Congress, the anti-kickback statute did not require that the conduct proscribed by the statute be knowing and willful.[43] Congress modified the anti-kickback statute, in response to concerns that criminal penalties may be applied to conduct that was not intended to violate the law,[44] requiring a knowing and willful violation of the statute.[45]

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39. 874 F.2d 20 (1st Cir. 1989).
40. *Id.* at 36.
41. OIG Management Advisory Report, *supra* note 4, at 28,415.
42. Hanlester, Docket No. C-448, Decision No. CR 181, at 56, *aff'd*, Docket No. C-448, Decision No. 1347, at 11.
43. Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419; *see generally* Stephen C. Pierce, United States v. Greber *and its Effect on the Medicare and Medicaid Programs*, 75 KY. L.J. 677, 680-94 (1986-87) (discussing the history of the scienter requirement in the anti-kickback statute).
44. H.R. REP. No. 1167, 96th Cong., 2d Sess. 59 (1980), *reprinted in* 1980 U.S.C.C.A.N. 5526, 5572.
45. Omnibus Reconciliation Act of 1980, Pub. L. No. 96-499, sec. 316, 94 Stat. 2599.

While the purpose of the knowing and willful requirement is to establish the element of scienter,[46] in reality a much more stringent scienter-type requirement is already present in the statute. As recognized by the court in *Bay State*, the offer, payment, solicitation, or receipt of remuneration does not violate the anti-kickback statute unless at least one purpose of the payment was to induce referrals.[47] This specific requirement imposes a much stronger showing of scienter than the traditional showing required to prove knowing and willful conduct. If a court concludes that at least one purpose of an offer, solicitation, payment, or receipt of remuneration was for the purpose of inducing referrals, almost certainly the knowing and willful requirement under the statute will have been satisfied.[48]

IV. Possible Safe Harbor Protection

As a result of the broad sweep of the anti-kickback statute, Congress directed DHHS to promulgate regulations that would establish "safe harbors" for certain business arrangements that would not be subject to prosecution. In response to Congress's directive, the OIG published eleven safe harbors that describe specific scenarios protected from fraud and abuse scrutiny. If the conduct complies with each requirement of a safe harbor provision, the conduct will not be subject to criminal prosecution or civil sanctions. While most arrangements will not comply with all the safe harbor requirements, these arrangements are not necessarily in violation of the statute. Arrangements not covered by the safe harbors may or may not violate the statute depending on the circumstances.[49]

Each safe harbor defines a situation or business arrangement in which payment will not be considered as remuneration under the anti-kickback statute. Three of the safe harbors, (1) personal services and management contracts, (2) space rental, and (3) equipment rental, are potentially applicable to business arrangements between hospitals and hospital-based physicians.[50]

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46. Bay State Ambulance, 874 F.2d at 33.

47. *Id.*

48. *Id.*

49. The general comments published in conjunction with the safe harbor regulations make it clear that business arrangements are not protected unless each of the individual conditions for the applicable safe harbor are met. The statute, not the regulations, define the scope of unlawful activities; the safe harbor regulations do not expand the scope of the anti-kickback statute. 56 Fed. Reg. at 35,952, 35,954.

50. 42 C.F.R. § 1001.952 (1991). The employee safe harbor, protecting the remuneration that flows between employer and employee, may also have some potential applicability in a limited number of states. However, in many states, the "corporate practice of medicine" doctrine prohibits the employment of physicians by non-professional corpora-

By structuring business arrangements to meet each of the required standards of either the personal services and management contracts,[51] space rental,[52] or equipment rental[53] safe harbor, hos-

tions, including hospitals. *See generally*, Alanson W. Willcox, *Hospitals and the Corporate Practice of Medicine*, 45 CORNELL L.Q. 432 (1960). Accordingly, the usefulness of the employee exception to the fraud and abuse statute may be limited.

51. There are six requirements that must be met for a business arrangement to fall within the personal services and management contracts safe harbor:

(1) The agency agreement is set out in writing and signed by the parties.
(2) The agency agreement specifies the services to be provided by the agent.
(3) If the agency agreement is intended to provide for the services of the agent on a periodic, sporadic or part-time basis, rather than on a full-time basis for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for such intervals.
(4) The term of the agreement is for not less than one year.
(5) The aggregate compensation paid to the agent over the term of the agreement is set in advance, is consistent with fair market value in arms-length transactions 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 made in whole or in part under Medicare or a State health care program.
(6) The services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law.

42 C.F.R. § 1001.952(d).

52. There are five requirements that must be met for a business arrangement to fall within the space rental safe harbor:

(1) The lease agreement is set out in writing and signed by the parties.
(2) The lease specifies the premises covered by the lease.
(3) If the lease is intended to provide the lessee with access to the premises for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such intervals.
(4) The term of the lease is for not less than one year.
(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions 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 made in whole or in part under Medicare or a State health care program.

Id. at § 1001.952(b). The term "fair market value" is defined in this subsection.

53. There are five requirements that must be met for a business arrangement to fall within the equipment rental safe harbor:

(1) The lease agreement is set out in writing and signed by the parties.
(2) The lease specifies the equipment covered by the lease.
(3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.
(4) The term of the lease is for not less than one year.
(5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business other-

pitals should be able to provide billing and management services, lease space, or lease equipment to a hospital-based physician group without risking a violation of the anti-kickback statute. However, these arrangements must be structured carefully to assure that (1) the hospital-based physicians pay fair market value for all services, space, and equipment, and (2) payment is not tied to the physicians' volume of business.

These three safe harbors are particularly useful in structuring business arrangements given the broad definition of remuneration that has been adopted by the federal circuit courts. Without safe harbor protection, common business arrangements under which hospital-based physicians agree to purchase billing or management services, lease space, or lease equipment from the hospital at fair market value could be held to violate the anti-kickback statute if one purpose of the arrangement was a subjective intent to induce referrals.

There is no safe harbor protection for an arrangement that requires hospital-based physicians to make payments that are unrelated to the provision of any goods or services by the hospital. In this type of arrangement, the hospital is essentially charging the physicians for the privilege of practicing at the hospital, the clearest example of the types of abusive arrangements that the anti-kickback statute is designed to prohibit. While there is no safe harbor protection where payments made to a hospital are based on the volume of business done by the physicians,[54] failure to comply does not render a violation. Each such transaction would have to be analyzed under the statute based on its circumstances. Finally, any arrangement not based on fair market value is inherently suspect given the fair market value requirement found in the safe harbor regulations and the courts' expansive definition of the term "remuneration" as used in the anti-kickback statute.

V. Offensive Use of the Anti-Kickback Statute: Relevant Litigation

At the time this article was written, two unusual cases dealing with the issue of potential fraud and abuse violations in business

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wise generated between the parties for which payment may be made in whole or in part under Medicare or a State health care program.

Id. at § 1001.952(e). The term "fair market value" is defined in this subsection.

54. 56 Fed. Reg. at 35,976. This type of arrangement is expressly excluded from safe harbor protection even where the hospital provides goods or services to the physicians at fair market value. *Id.* at 35,973, 35,985.

arrangements between hospitals and hospital-based physicians made their way into court.[55] In *Virginia Radiology Associates v. Culpeper Memorial Hospital*,[56] a hospital-based radiology group, Virginia Radiology Associates, brought a civil suit against Culpeper Memorial Hospital alleging that the hospital terminated the radiologists' privileges because they refused to participate in a kickback arrangement. The case was styled in part as a breach of contract action, and was not an attempt to seek private enforcement of the anti-kickback statute. The radiologists relied on the alleged violation of the anti-kickback statute to bolster their breach of contract claim.

Virginia Radiology Associates alleged that the hospital attempted to force the physicians to purchase practice management services from a hospital-owned company for a fee equal to fifty percent of Virginia Radiology Associates's billings in excess of $300,000 per year. Virginia Radiology Associates claimed that the practice management services were unnecessary, and that even if the services had been necessary, the hospital's fee far exceeded the fair market value of the services. Thus, according to Virginia Radiology Associates, the required contract term violated the anti-kickback law and the hospital's termination of Virginia Radiology Associates's privileges was improper. As of October, 1992, *Virginia Radiology* had not yet reached trial and was still pending in Culpeper County, Virginia circuit court.

In a case factually similar to *Virginia Radiology*, a hospital-based radiology group in California filed a civil suit against Anaheim General Hospital alleging that a marketing fee charged to the radiologist was actually a disguised kickback in violation of the anti-kickback statute.[57] The hospital terminated the radiologist's exclusive contract after the radiologist refused to pay the hospital an $8,000 monthly fee for marketing services. In response, the hospital claimed that the payments were required to lower the hospital's operational costs by asking the radiologists to cover some of the

55. In United States v. Kensington Hospital, 760 F. Supp. 1120 (E.D. Pa. 1991), the Justice Department brought an action under, *inter alia*, the Anti-Kickback Act of 1986, 41 U.S.C.A. § 51-58 (West 1987), alleging that the hospital required its physicians to "kick back" a percentage of their salaries as a "donation" to the hospital. The Anti-Kickback Act of 1986 regulates contractual relationships between government contractors and the federal government. The court dismissed the Anti-Kickback action, holding that Congress never intended it to apply to the types of relationships that exist between healthcare providers and the Medicare and Medicaid programs. 760 F. Supp. at 1140.

56. No. 90-L-172 (Cir. Ct. Culpeper County, Va., filed Aug. 8, 1990).

57. Pacific Coast Radiology v. Anaheim General Hosp., Case No. 666585 (Orange County Superior Ct., Cal., filed Aug. 22, 1991).

hospital's marketing costs. As of October, 1992, the case was still pending.

Both *Virginia Radiology* and *Anaheim General Hospital* are significant as they are both attempts by hospital-based physicians to use the anti-kickback statute offensively in civil actions between private parties. If the physician groups in these cases are successful, hospital-based physicians may have a tool with which to fend off attempts by hospitals to tap into the hospital-based physicians' revenues. Now that the OIG has formally taken the position that these types of business arrangements can violate the anti-kickback statute, hospital-based physician groups may become more aggressive in their use of the anti-kickback statute to avoid financial demands placed on them by hospitals.[58]

VI. Implications for Hospitals and Hospital-Based Physicians

The OIG made it clear that it believes certain business arrangements between hospitals and hospital-based physicians violate the anti-kickback statute.[59] While the report issued is not legally binding on either hospitals or physicians,[60] at present it appears that the courts may be inclined to agree with the OIG's position. Given the direction of the recent federal court decisions and the societal attitude toward increasing health care costs, the OIG may now be ready to test its position in the courts.[61] The possibility of OIG

58. William A. Gravely, Jr., the Chief Executive Officer of Culpeper Memorial Hospital, commented bluntly that he thinks physicians will use the OIG memorandum " 'as a club' " when negotiating their contracts with the hospitals. *OIG Memo Causes Concern*, *supra* note 8, at 68. " 'Any physician not inclined to talk about [a contract] is going to hit the [hospital] CEO with the OIG memo.' " *Id.*

59. Hospital-based physicians and hospitals in particular should also be wary of the recent attempts of the Internal Revenue Service ("IRS") to join the fraud and abuse enforcement effort. In a recent general counsel memorandum, the IRS ruled that a hospital may endanger its tax exempt status by entering into an arrangement that violates the anti-kickback statute. Gen. Couns. Mem. 39,862 (Nov. 22, 1991). While the ruling itself was limited to particular factual situations, it sets the tone for future fraud and abuse enforcement by the IRS. The IRS has focused increasingly on potentially abusive arrangements between non-profit hospitals and physicians. *See generally* Richard Pinto & Marsha Novick, *IRS Standards for Joint Ventures With For-Profit Partners*, J. Tax'n Exempt Organizations, Winter 1992, at 43.

60. The OIG does not have the authority to define illegal business arrangements. The Medicare Patient Protection Act of 1987 merely gives the Department of Health and Human Services the authority to impose civil sanctions for violations of the anti-kickback statute and to define certain arrangements that do not violate the statute, the safe harbor regulations.

61. The OIG recommended that the Health Care Financing Administration ("HCFA") instruct its intermediaries (i.e., private insurance companies that contract

action may be particularly likely now that the safe harbor regulations are established without a safe harbor to protect the types of suspect business arrangements between hospitals and hospital-based physicians discussed in the management advisory report.

The types of business arrangements prohibited under the anti-kickback statute involve the solicitation, receipt, offer, or payment of remuneration. Should the OIG initiate enforcement action targeted at a business arrangement between a hospital and hospital-based physicians, it is likely that both the hospital (as the party soliciting or receiving the remuneration) and the hospital-based physicians (as the party offering or paying the remuneration) would be named as defendants. The fact that the physicians may have entered into the arrangement begrudgingly may not go far in relieving the physicians of liability under the anti-kickback statute.

A successful suit by the OIG challenging a particular business arrangement between a hospital and a hospital-based physician group may also have an additional, potentially far reaching effect on joint venture arrangements involving hospitals and other health care providers.[62] For a court to hold that a particular business arrangement between a hospital and a hospital-based physician group violates the anti-kickback statute, the court must find that hospitals, in certain circumstances, constitute "referrers," as that term is used in the anti-kickback statute. In turn, such a finding would mean that in certain circumstances, hospital ownership in an independent outpatient facility could potentially violate the anti-kickback statute.[63]

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with HCFA to administer Medicare claims) to "refer cases similar to the examples given [in the report], or any other suspect arrangements to the OIG for possible prosecution or sanction." OIG Managment Advisory Report, *supra* note 4, at 28,417.

62. Abusive joint venture arrangements have traditionally been one of the prime targets of attack under the anti-kickback statute. *See generally* Robinson, *supra* note 23, at 1.

63. While a discussion of joint venture arrangements is beyond the scope of this article, it should be noted that the analysis of whether a hospital is a "referrer" in the context of a joint venture arrangement may differ from the analysis required in evaluating the types of business arrangements discussed in this article. A finding that a hospital is a referrer in the context of business arrangements between hospitals and hospital-based physicians would most likely be based on the indirect referral power flowing from the hospital's ability to control the "franchise" to provide hospital-based specialists' services within the hospital. On the other hand, a finding that a hospital is a referrer within the context of a joint venture would require a finding of a more direct type of referral power. In other words, the court would have to find that the hospital is in a position to directly influence the determination of where the patient goes to obtain healthcare services.

VII. CONCLUSION

The OIG has recognized that improper business arrangements between hospitals and hospital-based physicians can potentially impact the Medicare and Medicaid programs in at least three different ways.[64] First, these arrangements create a conflict of interest for the hospital. While a hospital's decision to award an exclusive contract to a hospital-based physician group should be based on the quality of services that the physicians can provide to the hospital's patients, business arrangements such as those discussed in this article create an incentive for the hospital to consider its own financial interests in awarding exclusive contracts to hospital-based physicians. Second, these arrangements tend to create an incentive for the hospital to encourage utilization of the hospital-based physicians' services, which can result in overutilization of certain services. The OIG noted that some of these types of arrangements may create an incentive for hospital-based physicians to attempt to recoup their "franchise fee" by encouraging unnecessary services. Finally, illegal arrangements can affect physician fees since the costs are inflated and do not reflect fair market value.

In their never ending search for revenue sources, hospital administrators may be tempted to "cash in" when determining which hospital-based specialists will provide services in their hospitals. However, any attempt to profit from these arrangements may come under OIG scrutiny and could result in civil sanctions or criminal prosecution for violation of the Medicare and Medicaid anti-kickback statute.

64. OIG Management Advisory Report, *supra* note 4, at 28,416 to 28,417.