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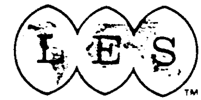
Anti-Kickback Statute Broad, Easy to Violate

BY J. MARK POHL*



Although many violations may be technical and not prosecuted, the resulting contracts may be illegal

Entities that "knowingly and willfully" pay to induce business reimbursed under Medicare are criminally liable. The law is extremely broad. Prohibited conduct includes paying another entity for recommending the purchase of any good reimbursable by Medicare.

This crime is codified in Section 1128(b) of the U.S. Social Security Act, 42 U.S.C.A. § 1320a-7b (the "Medicare-Medicaid anti-kickback statute"). The offense is classified as a felony. It is punishable by fines of up to $25,000 and imprisonment for up to five years. Further, violators may be excluded from certain Federal health care programs.

STATUTORY EVOLUTION

the anti-kickback statute is intended to combat financial incentives for ordering goods which patients do not require. *United States v. Greber*, 760 F.2d 68, 71 (3rd Cir. 1985). When such goods are paid for by a "Federal health care program," the purchases present a drain on the Federal health-care system. The "anti-kickback statute" thus generally combats over-use of Medicare reimbursed goods.

The statute was, for a time, limited to "bribes" and "kickbacks" as those terms are defined by the common law. Under the common law, a "bribe" requires "the element of corruption, breach of trust, or violation of duty." *Glengariff Corp. v. Snook*, 471 N.Y.S.2d 973 (Sup. Ct. 1984). An actionable duty of trust could be found in the physician-patient relationship. *United States v. Hancock*, 604 F.2d 999, 1001 (7th Cir. 1979).

Other relevant relationships, however, did not necessarily entail such a legal duty of trust. For example, increased use of Medicaid reimbursed goods might be promoted by a pharmaceutical manufacturer hiring an independent contract sales organization. Because the relationship between manufacturer and sales organization does not necessarily involve a legally-cognizable duty of trust, a payment under such a relationship is not necessarily a "bribe."

Similarly, the statute also covered "kickbacks." A kickback is a payment for which no service had been rendered. *Greber*, 760 F.2d at 72; *see also United States v. Tapert*, 625 F.2d 111 (6th Cir. 1980). Thus, payment for service rendered, even if the service promotes the over-use of Medicare reimbursed goods, would not be a "kickback."

Where the payments were neither bribe nor kickback, they were not culpable. *Hancock*, 604 F.2d at 1001; *Glengariff Corp.*, 471 N.Y.S.2d 973; *United States v. Porter*, 591 F.2d 1048 (5th Cir. 1979); *Bethune Plaza, Inc. v. State of Illinois*, 414 N.E.2d 183 (Ill. App. 1980); *United States v. Zacher*, 586 F.2d 912, 915 (2nd Cir. 1978). Thus, many commercial arrangements that the government found economically objectionable were not found to entail a "bribe" or a "kickback," and thus were not found illegal. *See id.*

To address a "growing problem of fraud and abuse in the system" and to "remedy the deficiencies in the statute," Congress amended the statute. *Greber*, 760 F.2d at 71. The amended statute encompasses kickbacks and bribes, as well as "remuneration" generally. 42 U.S.C. § 1320a-7b(b). Thus, one may now violate the anti-kickback statute without having a "bribe" or "kickback." *Modern Medical Laboratories, Inc. v. Smith-Kline Beecham Clinical Laboratories, Inc.*, 1994 WL 449281 at *3 (E.D.Ill. 1994), *Nursing Home Consultants, Inc. v. Quantum Health Services, Inc.*, 926 F.Supp. 835, 843 (E.D. Ark. 1996), *aff'd*, 112 F.3d 512 (8th Cir. 1997) (per curiam) (unpublished).

We herein first review the scope of the statute, and discuss some examples of commercial arrangements that now fall within its scope. Next, we discuss the availability of certain exemptions.

STATUTORY SCOPE

To more precisely explore what the statute covers, we should read it. It provides:

(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

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any person to induce such persons —

(A) to refer to 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.

42 U.S.C.A. § 1320a-7(b) (1997. The statute thus criminalizes both the receipt and the payment of illegal remuneration.

Of the statutory elements, several deserve elaboration. First, the statute is limited to remuneration — transfers of value between discreet legal persons. Second, the "gravamen" of the statute is "inducement." Third, while the statute literally requires "willfulness," its application in fact is not so limited. Fourth, the statute covers any culpable person — not just physicians. Finally, the statute requires strict compliance — there is no exception for *"de minimis"* violations.

Remuneration

The statute is limited to remuneration — *i.e.* transfers of value to another legal person. Thus, the statute is not implicated when payments are transferred within a single entity. Department of Health & Human Services, Office of Inspector General (the "OIG"), *Notice of Final Rule,* 56 Fed. Reg. 35952, 35983 (1991). For example, funds transfers from one division of an entity to another division are outside the statute.

However, when funds transfers are made among distinct legal entities, the statute is implicated. *Id.* This remains true even if the payments are "between entities with common ownership." *Id.* Thus, for example, "payments between wholly-owned subsidiaries" and other "payments between entities where exclusive ownership and control is present" are within the statute. *Id.* Similarly, the statute covers joint-venture arrangements. *See generally,* Office of Inspector General (HHS), *Special Fraud Alerts* (Dec. 19, 1994).

The statute encompasses "remuneration" in any form. That term includes cash payment. It also includes, for example, purchase discounts. *Final Rule,* 56 Fed. Reg. at 35983. Thus, marketing arrangements among commonly-owned subsidiaries in a single corporate family may be within the ambit of the statute, even where no cash is exchanged.

The legal form of the arrangement may not save it from illegality. A marketing arrangement can violate the law regardless of whether the arrangement is structured as a marketing-services contract, a "joint venture," or a factoring-type arrangement wherein the manufacturer pays a percentage of accounts receivables collected. *See* Thornton, D.M., "letter re Advisory Opinion No. 98-1" (March 19, 1998) at footnote 7.

Inducement

The gravamen of a violation of the statute is "inducement," not necessarily the structure of the arrangement. *Final Rule,* 56 Fed. Reg. at 35955. "Inducement" describes the intent of those who offer or pay remuneration in paragraph (2) of the statute. *Id.* at 35958. The term "induce" is used in the ordinary dictionary definition: "to lead or move by influence or persuasion." *Id.*

Thus, if the nature of the agreement is such that payments are intended to induce referrals, the anti-kickback law applies. Office of The Inspector General, Department of Health & Human Services, *Proposed Rule,* 54 Fed. Reg. 3088, 3091 (January 23, 1989).

In contrast, where the arrangement provides for only "limited" promotional support, the arrangement may not violate the law. *See* Thornton, D.M., "letter re: Advisory Opinion No. 98-2" at pg. 2, §I ¶1 (April 8, 1998).

Inducement is not limited to inducing patients. The statute "criminalize[s] broker-style arrangements whereby one entity receives remuneration for placing business with another entit *Modern Medical,* 1994 WL 44928 *3. The statute thus covers pers who pay to induce business fr other businesses.

For example, in *United State Bay State Ambulance & Hospital R tal Service,* 874 F.2d 20 (1st (1989), the person receiving muneration did not receive muneration for referring patient the ambulance service. Rather, received remuneration from ambulance service for using position in the hospital bid comr tee to award the city and hosp ambulance contract to Bay Sta Because he "induced" the hosp bid committee, he was fou criminally liable under the statu

We now review two cases t find agreements which violate statute. These two cases are *Mod Medical Laboratories, Inc. v. Smi Kline Beecham Clinical Laborator Inc.,* 1994 WL 449281 (E.D.Ill. 199 and *Nursing Home Consultants, I v. Quantum Health Services, Inc.,* 9 F.Supp. 835, 843 (E.D. Ark. 199 *aff'd,* 112 F.3d 512 (8th Cir. 19 (per curiam) (unpublished).

Modern Medical involved a "C Operative Management Agre ment" wherein Smith-Kline w paid to "market, manage a operate" Modern Medica laboratory business and faciliti *Id.* at *1. Work was performed, a payments were made, according the terms of the agreement. Such work included, per the co tract, marketing Modern Medica laboratory services. *See Id.*

Performance occurred "for sor time." Id. Then, Smith-Kline adv ed Modern Medical that it wou not make further payment because Smith-Kline believed th agreement could be illegal und the anti-kickback statute. *Id.*

The court held that the agreeme violated the anti-kickback statut *Id.* at *4. The statute "reaches a tivity whereby one entity receiv remuneration for essentially takir the physician's 'order'... and a ranging for another entity" supply the good or service. *Id.* at * The court found that Mode Medical arranged for the Medicai reimbursable good or service to b purchased from Smith-Kline, an

received remuneration for that. *Id.* at *3.

In *Quantum Health Services, Inc.*, 926 F.Supp. 835, Quantum supplied reimbursable medical equipment and supplies to nursing home patients. *Id.* at 838. To broaden its sales in a certain geographic market area, Quantum enlisted the services of Nursing Home Consultants ("NHC").

NHC marketed medical supplies and equipment on behalf of other companies to nursing home residents. *Id.* at 838. NHC thus acted as marketing intermediary between the nursing home residents (who were covered by Medicare), and medical suppliers, whose products were paid for by the residents' Medicare coverage. *Id.* at 838.

Under the contract with Quantum, NHC identified Medicare recipients who needed Quantum's medical supplies and put these recipients in contact with Quantum. *Id.* at 839. Quantum then sold its products directly to the nursing home, on behalf of the residents. *Id.* at 839.

The marketing contract detailed the sales procedures to be followed, and said that all orders were to be made directly with Quantum. *Id.* at 839. NHC could thus only provide the appropriate documents, but could not otherwise assist a resident in connection with his placing an order. *Id.* at 839. The contract mandated that if either party breached these "order taking procedure and service guidelines," the other party could terminate the contract. NHC thus had no direct involvement in the actual sales of the medical supplies to nursing home residents. *Id.* at 839.

The court held that the contract was illegal under the anti-kickback statute. *Id.* at 844.

The court discussed two ways the contract could create illegal "inducement." First, NHC was paid for referring persons who needed Medicare-covered supplies to Quantum. In turn, Quantum sold the residents those supplies (via their nursing homes). The court found this type of relationship falls squarely within" the inducement prohibited by subparagraph A of the statute. *Id.* at 843.

Second, NHC could be viewed as paid for recommending to Medicare recipients that they purchase their Medicare-reimbursable supplies from Quantum. As such, the relationship with Quantum would violate subparagraph B of the statute. *Id.* at 843.

The Office of Inspector General recently affirmed the potential for nursing homes to violate the anti-kickback statute by, *inter alia*, granting an "exclusive or semi-exclusive" license to a subcontractor, to provide needed goods or services. *See* Office of Inspector General, *Special Fraud Alert*, "Fraud and Abuse in Nursing Home Arrangements..." (March 1998).

Willfulness

In addition to "remuneration" and "inducement," the statute expressly requires that the actor act "knowingly and willfully." Thus, this element would seem to be required for the government to prosecute a person under the statute. Willfulness, however, is not required to make a contract illegal under the statute.

For example, in *Modern Medical*, 1994 WL at 449281, there is no mention of either party's "willfulness." Rather, the court's opinion implies that both parties were completely unaware of the anti-kickback statute on signing the contract, and continued to be so until SmithKline discovered the possible violation. The court nonetheless found the contract illegal. In doing so, the court noted that "performance of the contract after this ruling would definitely constitute a knowing and willful violation and thus, future performance would be illegal." *Id.* at *4.

Similarly, in *Quantum Health Services*, it was not clear that anyone actually intended to violate the statute. *Quantum*, 926 F.Supp. at 843, n.18. The court "could not say that anyone is criminally liable." *Id.* Even without culpable intent, however, the court held the Marketing Agreement illegal. The court noted "the subject matter of the Marketing Agreement is contrary to the public policy of the . . . statute." *Id.* This remains true "irrespective of whether anyone can be prosecuted criminally (or civilly) in connection with that agreement." *Id.*

While the court in Quantum did not actually find willfulness, it was potentially implicit in that situation. Prior to the execution of the marketing agreement, Quantum's president received legal advice indicating that the agreement's per-item fee structure was likely in violation of the Medicare statute. *Quantum*, 926 F.Supp. at 846. It was "far from clear" that Quantum's president was, in fact, convinced that the legal opinion was correct. *Id.* However, while negotiating the marketing agreement, Quantum's president told NHC's president that the compensation scheme may be in violation of the Medicare law. Thus, the principals involved knew that the arrangement might be illegal. *Id.* at 847. The court noted, "If people knew that, even if they had executed an agreement prohibited by the Medicare statutes, the courts would nevertheless allow them to recover the benefit of their illegal bargain, what would deter them from entering into such arrangements in the first place?" *Id.* at 847.

Culpable Actors and "Technical Violations"

The statute is not limited to physicians. *Modern Medical*, 1994 WL 449281 at *2; *Quantum*, 926 F.Supp. at 843, n.20. Rather, "whoever" does prohibited acts is liable. *Modern Medical*, 1994 WL 449281 at *2. Thus, the reported cases are not universally limited to physicians or others who have a direct role in the provision of health-care services. *Quantum*, 926 F.Supp. at 843, n.20.

Arrangements that do not include direct health-care providers, however, might not warrant criminal prosecution. Such can be the case where the activities do not involve direct contact with program beneficiaries. *Final Rule*, 56 Fed. Reg. at 35954. Alternatively, prosecution may not be warranted where the person involved in these promotions is not involved in the delivery of health care, and thus is not in a relationship of trust and confidence with patients. *Id.* Thus, while many marketing and advertising activities

may involve "at least technical violations of the statute," in practice, many of these activities "do not warrant prosecution." *Id.*

Note, however, that there is no express statutory or regulatory exemption for such "technical violations"; they are still violations. A given technical violation's legal effect will thus depend on the particular facts of each case. Thus, while a "technical violation" might "not properly form the basis of a criminal (or civil) prosecution by the government," such a violation remains a violation and is nevertheless illegal. *Quantum,* 926 F.Supp. at 844, n.21.

There Is No De Minimis Exception

The statute covers transactions "for which payment may be made in whole or in part" by Medicaid. 42 U.S.C.A. §1320a-7b (b) (1) (A), (B) and (2) (A) (B) (1996). The statute does not excuse transactions where only part of the goods are paid for by Medicaid. Thus, for example, where only "some" of the service is reimbursed, there is a violation. *Modern Medical* at *3.

Similarly, the statute does not excuse remuneration paid partly for illegitimate inducement, and partly for another, legitimate purpose. For example, in *Quantum Health Services,* the marketing agent's performance included (illegitimate) marketing, but also allegedly included legitimate services, such as maintaining inventories and troubleshooting (such as returning unordered products). *Quantum,* 926 F.Supp. at 843, n.19. Including legitimate services "is of no moment," and whether compensation is strictly for illegal activity is "irrelevant." *Id.* If compensation is based even in part for prohibited inducement, the agreement violates the statute. *Id.*

The Anti-Kickback Statute Has Certain Exceptions

The statute recites several exceptions. The anti-kickback statute shall not apply to --

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

***

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient Program Protection Act of 1987; and

(F) any remuneration between an organization and an individual or entity providing items or services . . . if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide.

42 U.S.C.A. § 1320a-7b (b) (3) (1997).

Thus, the statute exempts both eligible employees and certain payment practices under service contracts with independent contractors. We both of these in turn.

BONA FIDE EMPLOYEES

Bona Fide Employees Are Exempt

The statute excepts payments to employees. The term "employee" must meet the Internal Revenue Service definition, at 26 U.S.C. § 3121(d)92), 42 C.F.R. § 1001.952(i) (1996). If the person meets this definition, his or her activities are excepted from the anti-kickback statute.

This remains true even if the employee is paid a sales-based commission. Further, this remains true even if that employee is "a part-time employee paid on a commission-only basis." *Final Rule,* 56 Fed. Reg. at 35981. As long as a bona fide employer-employee relationship exists between the part-time employee and the employer, the relationship falls within the scope of the employee exception. *Id.*

Independent Contractors Are Not Exempt

In contrast to employees, independent contractors do not qualify for the exception. This is because of alleged "widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control." *Final Rule,* 56 Fed. Reg. at 35981. Thus, if salespersons are paid on the basis of the amount of business they generate, to be exempt from civil or criminal prosecution, the principal "should make these salespersons employees." Office of Inspector General (HH *Notice of Proposed Rule,* 54 Fed. R 3088, 3093 (1989).'

It has been argued that propriate supervision and contro independent contractors can be by including restrictive terms in agency agreement. *Final Rule,* Fed. Reg. at 35981. Further, cert pharmaceutical marketing activit are already controlled by otl Federal Statutes. *See e.g.,* U.S.C.A. §§ 331(k) (prohibiti material alteration or obliteration drug labeling); 331(o) (prescripti drug distributors must give gove ment-approved packaging inse to physicians, on request). Th the safe harbor might in the fut be expanded to include indepe dent contractor commission-sa contacts. This will happen or after the OIG "can predict wi reasonable certainty" that co mission-sales contracts will not abusive. *Final Rule,* 56 Fed. Reg. 35981. For now, the definition "employee" does not include i dependent contractors paid on commission basis. *See id.*

PERSONAL SERVICE CONTRACTS

The statute prohibits remuner tion for "recommending purcha ing or ordering" reimbursab items. Thus, marketing and adve tising activities by nonemploye may involve at least "technic violations" of the statute. Thu concern had arisen among a nun ber of health-care providers th many relatively innocuous or eve beneficial commercial arrangemen would be technically covered by th statute and subject to criminal pro ecution. *Proposed Rule* at 308 Similarly, many of these adverti ing and marketing activities ar "technical violations" that do no warrant prosecution.

To protect innocuous and benef cial arrangements, Congress gav the Secretary of Health and Huma Services, in consultation with th Attorney General, authority t promulgate safe harbor exemp tions. *See* 101 Stat. 680, 697 (198 (the "Medicare and Medicaid Pa tient and Program Protection Act c

1987"). The Secretary of Health and Human Services has accordingly promulgated a safe harbor regulation for certain service contracts.

The Regulation Language

The safe harbor regulation enumerates six elements. I will take the liberty of rearranging their order, to facilitate our discussion. The regulation (as rearranged) provides:

(b) Personal services and management contracts. As used in section 1128B of the Act, "remuneration" does not include any payment made by a principal to an agent as compensation for the services of the agent, as long as all of the following six standards are met --

(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.

(4) The term of the agreement is for not less than one year.

(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.

(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.

(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.

For purposes of paragraph (d) of this section, an agent of a principal is any person, other than a bona fide employee of the principal, who has an agreement to perform services for, or on behalf of, the principal.

42 C.F.R. § 1001.952(D) (Oct. 1, 1996).

This safe harbor provision may be useful where the parties cannot enter into commission sales arrangements that do not comply with the IRS definition of "employee." *Final Rule,* 56 Fed. Reg. at 35981.

This exemption is available only for arrangements that comply with every one of the six elements enumerated. Several of these elements are noteworthy. Saliently, the safe harbor does not apply if the compensation paid "takes into account the volume or value of any referrals or business otherwise generated." We discuss each of these six elements in turn.

The Compensation Cannot Be Calculated on Sales Volume

The safe harbor applies only if the compensation paid does not "take [] into account the volume or value of any referrals or business otherwise generated between the parties." Thus, there is an implicit or explicit arrangement where the amount of the payment varies based on sales volume or value, the safe harbor does not apply. *Proposed Rule,* 54 Fed. Reg. at 3091.

For example, in *Modern Medical,* the agreement mandated that the marketing agent would take a fixed percentage (90%) of the total revenue obtained, remitting the remainder to the facility owner. The agreement thus gave the marketing agent a percentage of all "Federal health-care program" revenues obtained. *Modern Medical,* 1994 WL 449281 at *1. The court held that this arrangement for compensation took into account the value of the referrals or business generated between the parties, and thus failed to qualify for the safe harbor provision.

Similarly, in *Quantum Health Services,* 926 F.Supp. 835, the marketing agent's compensation was based on the number of sales made by the principal, rather than based on a predetermined annual fee. *Quantum,* 926 F.Supp., at 841. The court held, "the Marketing Agreement, by virtue of its compensation scheme, falls directly within the class of transactional relationships prohibited by" the anti-kickback statue. *Quantum* at 842-43. Because the compensation was based on sales volume, the agreement did not quality for the safe harbor. *Id.* at 844. The court noted that the marketing agreement "may not, in the purest sense, be a commission sales agreement." *Id.* at 844, n.21. Since the marketing agent received a flat fee for each item sold, however, it effectively received a percentage commission on those sales, the percentage being the fee divided by the item's total cost. *Id.* at 844, n.21.

Similarly, in *United States v. Kats,* 871 F.2d 105 (9th Cir. 1989) (per curiam), the owner of a testing-lab referral service was paid 50% of the amount received from Medicare and MediCal (a state program). He was convicted of violating the anti-kickback statute. The Ninth Circuit affirmed, finding such revenue-sharing actionable. *Id.* at 109.

Commission sales agreements may thus not meet the safe harbor provisions. *See Final Rule,* 56 Fed. Reg. at 35974. It has been argued that independent contractors should be given specific protection for commission sales arrangements, because they merely replicate with an independent contractor an economic arrangement that is valid with an employee. *See id.* The Office of Inspector General expressly rejected this approach, concluding that there "is no reason for treating commission sales agreements differently under these regulations from other types of contracts for personal services performed by independent contractors." *Id.*

One Year Minimum Term

The regulation requires a one-year minimum contract term.

This element addresses a concern for abuse resulting from the periodic renegotiation of ostensibly short-term contracts, in response to changing referral volumes. *Final Rule,* 56 Fed. Reg. at 35973. For example, if the renewal contracts frequently alter the remuneration quantity, the volume or value of referrals can influence the size of the payments under the renewed contract. *Id.*

The one-year requirement restricts the period within which contract terms may not be changed. *Id.* It does not restrict the time within which services under the contract may be performed. *Id.* Thus, so long as contract terms are not altered within a one-year period, an agreement that is performed in less

than one year's time will meet the one-year requirement in the safe harbor provision. *Final Rule,* 56 Fed. Reg. at 35973. Thus, the rule allows for the performance of activities or services that, by their very nature, take less than one year. *See id.*

The one-year minimum term impacts the legality of "early termination" clauses. The legitimacy of such clauses depends on the parties' intent. *Final Rule,* 56 Fed. Reg. at 35973-74. Termination "for cause" clauses should not jeopardize safe harbor status, if the clauses are (i) drafted "in compliance with Internal Revenue Service or other legal or regulatory requirements," and if (ii) the intent of the termination clause is "to comply with those requirements, and not to facilitate renegotiation of contract terms." *Final Rule,* 56 Fed. Reg. at 35974.

The first element of this test is not onerously restrictive. It allows any clause that is drafted to comply with "legal requirements." This potentially allows for any clause intended to create termination rights enforceable under the "legal requirements" of applicable contract law. Such an allowance would seem broad enough to negate the safe harbor element altogether.

In practice, however, such an approach, if abusive, is unlikely to pass muster, as the test also includes the second element, the parties' subjective "intent." Thus, if a contract is terminated under a termination clause, the failure to renew the contract shows that the termination was effectuated for a legitimate purpose. *Id.* (emphasis added). By implication, if a contract is terminated and then renewed (or renewed without prior termination, if termination could be used as a threat) could show that the termination clause was for an illegitimate purpose. *See id.* This seems especially likely if renewals are correlated to payment adjustments based on sales volume.

Intermittent Service Must Be Specified

The contracted-for service can be provided on a periodic, sporadic or part-time basis. The agreement must, however, specify in advance the precise timing and duration of the periods of service, and the compensation for each period. The personal services agreement must thus provide a schedule of intervals and their precise length, and payments for the intervals.

This is because, as with contracts for less than one year, part-time contractual arrangements are considered especially vulnerable to abuse. This is because they are subject to modification based on changing referral patterns between the parties. *Id.* For example, an optometrist who pays *ad hoc* "rent" to an ophthalmologist for the time spent in the physician's office examining only referred patients, pays rent (remuneration) that varies based on referral volume. *Id.* This is impermissibly paying for the referrals. *Id.*

To avoid the potential for abuse inherent in part-time business arrangements between parties in actual or potential referral relationships, safe harbor protection is limited to contracts that set forth in advance the timing, frequency, and length of services or internals of use.

It has been argued that under periodic contract arrangements, the exact compensation for each interval cannot always be specified in advance. It has also been noted that furnishing professional services on an "as needed" basis is a commercially acceptable, cost-effective business practice that should be protected so long as the rate of compensation is commercially reasonable. *Final Rule,* 56 Fed. Reg. at 35974. Thus, requiring specificity of time intervals and compensation as conditions for safe harbor protection may interfere with the flexibility necessary to accommodate changing demand, and may increase costs in situations where the demand proves lower than expected at the time the contract was made. *See id.*

Parties may be unable to specify in advance the timing or duration of such part-time business arrangements, or the precise compensation involved. For example, compensation under a contract requiring the furnishing of supplies and the hiring of personnel may vary depending on the costs of the supplies and number of personnel. Similarly, a drug manufacturer r contract with a marketing organ tion to pay a specific amount hour of marketing service prov ed, without being able to anticip the scheduling of services in vance. *See id.* Such arrangeme do not qualify for the safe harb

The Arrangement Must Be Othen Legal

The safe harbor does not prot the promotion of a business rangement that violates other la This is because there apparen have been instances of marketi activities that encourage others violate the statute. *Final Rule,* Fed. Reg. at 35974. It has be found inappropriate to allow su activities to receive safe harbor p tection. Thus, the counseling promotion of an activity which its constitutes a violation of any Sta or Federal law is not a violation the statute.

Must Be in Writing and Spec Services

The agreement must be in writi and signed by the parties. Th generally is in accord with both t statute of frauds, which requir that contracts not performable wit in a year be in writing, and wi certain state law requirements th contracts over a certain dollar valu must be in writing. The agreeme must also specify the services to b provided.

SUMMARY

The anti-kickback statute broad, and the exemptions narrov The law is thus easy to violate While many violations may b "technical" and thus not warrar prosecution by the Office of Inspec tor General, violative contracts ar nonetheless illegal. As such, the may be unenforceable. This ma create economic exposure *vis* th other party to the contract. It ma also create legal liability to third par ties (*e.g.* investors who relied on material, invalid contact in in vesting in a party thereto) or othe government agencies (the Secur ities & Exchange Commission).