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Health Care Marketing Under the Anti-Kickback Statute

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I. INTRODUCTION

Marketing efforts by health care providers have historically presented one of the most sensitive areas under the federal health care anti-kickback statute, 42 U.S.C. §1320a-7b(b) (the "anti-kickback statute"). Recently-enacted regulations relating to the anti-kickback statute impact indirect health care providers. As such, the anti-kickback statute potentially excludes major manufacturers of pharmaceuticals, medical equipment and medical goods from participating in federal health care programs. Consequently, products manufactured by these entities would not be reimbursable.[1] This article will provide a legal overview of the anti-kickback statute and its so-called safe harbors. Furthermore, it will analyze the Department of Health and Human Services' Office of Inspector General's ("OIG") interpretation and application of the statute to marketing relationships. It will then look at the evolution of these interpretations to provide guidance in structuring relationships between health care providers and marketers in order to minimize the possibility of prosecution under the statute.

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1 *See* Health Care Programs: Fraud and Abuse; Revised OIG Exclusion Authorities Resulting from Public Law 104-191, 63 Fed. Reg. 46,676, 46,678 (1998) (codified *at* 42 C.F.R. pt. 1000.10).

II. ANTI-KICKBACK STATUTE

The federal health care anti-kickback statute is far broader than many health care providers realize. It establishes criminal and civil penalties for persons who "knowingly and willfully" offer, pay, solicit or receive any remuneration, directly or indirectly, in cash or in kind, in return for referrals of goods or services that may be paid for, in whole or in part, by a federal health care program, including the federal Medicare program or a state Medicaid program. The statute also prohibits remuneration to induce referrals to purchase, lease, order, arrange for or recommend the purchasing, leasing, or ordering goods or services payable by a federal health care program. Because the statute is so broad, prohibiting "arranging for or recommending purchasing, leasing or ordering," it appears to prohibit most marketing activities by its very terms. As the OIG has noted:

> . . . we believe that many marketing and advertising activities may involve at least technical violations of the statute. We, of course, recognize that many of these activities do not warrant prosecution in part because (1) they are passive in nature, i.e., the activities do not involve direct contact with program beneficiaries, or (2) the individual or entity involved in these promotions is not involved in the delivery of health care. Such individuals or entities are not in a position of public trust in the same manner as physicians or other health care professionals who recommend or order products and services for their patients.[2]

In 1987, responding to health care providers' claims that the broad scope of the anti-kickback statute created an uncertain climate in which to conduct business, Congress created four statutory exceptions to the statute[3] and directed the OIG to issue "regulations specifying payment practices that will

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[2] Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,974 (1991) (codified at 42 C.F.R. pt 1001).

[3] The four original statutory exceptions to the anti-kickback statute are for

(1) discounts or reductions in price if properly disclosed and appropriately reflected in costs claimed or charges made;

(2) payments to employees under a *bona fide* employer/employee relationship;

(3) certain payments by vendors to group purchasing organizations; and

(4) waiver of coinsurance for certain limited Medicare Part B services by a federally qualified health care center with respect to an individual who qualifies for subsidized services under a Public Health Service Act program.

42 U.S.C. § 1320a-7b(b)(3) (1999).

not be subject to criminal prosecution under the [anti-kickback] statute and that will not provide a basis for exclusion from participation in Medicare or State health care programs.[4] Subsequently, in 1996, Congress, in passing the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created another exception for risk-sharing arrangements.[5]

The OIG has promulgated a number of safe "harbor regulations" defining conduct that will not violate the statute.[6] For purposes of this article, the most relevant of these are the safe harbor for employees and the safe harbor for personal services and management contracts.[7] The employee safe harbor is relatively straightforward: it provides that payment by an employer to an employee who has a bona fide employment relationship with the employer for the provision of items or services for which payment may be made in whole or in part under Medicare or a State Medicaid program does not constitute "remuneration" for purposes of the anti-kickback statute.[8] The safe harbor for personal services or management contracts is more involved. To be afforded safe harbor protection, an arrangement must meet each of the following six standards:

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[4] Section 14(a) of the Medicare and Medicaid Patient Protection Act of 1987, P.L. 100-93, codified at 42 U.S.C. § 1320a-7b(b)(3)(E) (1999) and 42 C.F.R. § 1001.952. This act also expanded civil money penalties and assessments, and expanded mandatory and discretionary exclusions. Subsequently, Section 216 of the Health Insurance Portability and Accountability Act created an additional exception for certain risk-sharing arrangements. *See* 42 U.S.C. § 1320a-7b(b)(3)(F) (1999).

[5] Health Insurance Portability and Accountability Act of 1996, § 216, Pub. Law 104-191 (Aug. 21, 1996) *codified at* 42 U.S.C. § 1320a-7b(b)(3)(F) (1999).

[6] There are currently thirteen final regulatory safe harbors that apply to the following categories of arrangements:

1. investment interests in large publicly-traded entities or certain small entities;
2. space rentals;
3. equipment rentals;
4. personal services and management contracts;
5. sale of practice;
6. referral services;
7. warranties;
8. discounts;
9. employees;
10. group purchasing organizations;
11. certain Medicare Part A waivers of coinsurance and deductibles;
12. increased coverage, reduced cost-sharing amounts, or reduced premium amounts offered by certain health plans; and
13. price reductions offered to certain health plans.

42 C.F.R. § 1001.952 (1998).

[7] Because the focus of this article is upon contractual relationships between a health care provider and a marketing company, this article will not analyze the potential impact of the employee statutory exception and safe harbor, 42 C.F.R. § 1001.952(i) (1998).

[8] 42 C.F.R. § 1001.952(i) (1998).

a. the agreement is set out in writing and signed by the parties;
b. the agreement specifies the services to be provided by the agent;
c. if the 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 bases for the term of the agreement, the agreement specifies exactly the schedule of such intervals, their precise length, and the exact charge for each such interval;
d. the term of the agreement is for not less than one year;
e. the aggregate compensation paid 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; and
f. 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.[9]

Failure to meet the requirements of a particular safe harbor does not mean that an arrangement is *per se* illegal. Rather, in such a situation, the OIG will analyze the particular facts and circumstances underlying the arrangement to determine its legality.[10]

Violations of the anti-kickback statute constitute a felony punishable by a maximum fine of $25,000, or imprisonment for up to five years, or both.[11] Additionally, any individual or entity that is criminally convicted of violating the anti-kickback statute will be automatically excluded from participation in the Medicare, Medicaid, or any other federally-funded health care program.[12] Moreover, the OIG also may seek to exclude an individual or entity that has

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[9] 42 C.F.R. § 1001.952(d) (1998).

[10] As the OIG noted in the preamble to the safe harbor regulations, the failure of an arrangement to comply with a safe harbor can mean one of three things. First, it may mean that the arrangement is not intended to induce the referral of business reimbursable under Medicare of Medicaid, so there is no reason to comply with the safe harbor standards, and no risk of prosecution. Second, the arrangement could be a clear statutory violation, and prosecution would be "very likely." Third, the arrangement may violate the statute in a less serious manner, although it might not be in compliance with a safe harbor provision. In such instances, the preamble indicates that there would be "no way" to predict the degree of risk. *See* Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,954 (1991) (to be codified at 42 C.F.R. pt. 1001)

[11] 42 U.S.C. § 1320a-7b(b)(1)(B) (1999).

[12] 42 U.S.C. § 1320a-7(a)(1) (1999).

violated the anti-kickback statute through an administrative proceeding, irrespective of any criminal charges.[13] Finally, under statutory amendments promulgated pursuant to the Balanced Budget Act of 1997, the OIG may impose upon or assess from, any individual or entity violating the anti-kickback statute civil money penalties of up to $50,000 per violation or up to three times the total amount of a kickback paid regardless of the legitimacy of any remuneration.[14]

III. CASE LAW

In interpreting the federal anti-kickback statute for purposes of imposing civil or criminal penalties or exclusions, courts have held that the statute is very broad in scope and encompasses any arrangement where a purpose of the remuneration is to obtain money for the referral of services or to induce further referrals.[15] Also, the anti-kickback statute does not define the terms "knowingly" and "willfully." As a result, courts have interpreted these words in a variety of ways for purposes of applying the statute to a particular arrangement.[16] Although none of these court decisions relates to a marketing relationship *per se*, it is clear that there is a trend toward interpreting the anti-kickback statute broadly for purposes of exclusion or imposing civil or criminal penalties.

Although there is currently no case law concerning governmental actions to impose penalties under the anti-kickback statute, several civil lawsuits have

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[13] 42 U.S.C. § 1320a-7(b)(7) (1999).

[14] 42 U.S.C. § 1320a-7a(a)(7) (1999).

[15] *See, e.g.*, United States v. Greber, 760 F.2d 68 (3d Cir.), *cert. den.*, 474 U.S. 988 (1985); United States v. Kats, 871 F.2d 105 (9th Cir. 1989)(adopting *Greber's* "one purpose test").

[16] *See, e.g.*, United States v. Levin, 973 F.2d 463 (6th Cir. 1992), *reprinted in* Medicare and Medicaid Guide (CCH) [Transfer Binder 1992-2] ¶ 40,461 (dismissing anti-kickback prosecution where HHS previously approved the marketing practice in question, on the ground that prior approval made it impossible to establish requisite criminal intent); Hanlester Network v. Shalala, 51 F.3d 1390, 1400 (9th Cir. 1995) (stating that "knowingly and willfully" requires defendants to (1) know that the anti-kickback statute prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with specific intent to disobey the law); United States v. Neufeld, 908 F. Supp. 491, 497 (S.D. Ohio 1995) (refusing to adopt the *Hanlester* definition of "willfully" but also hesitating from "embarking on an exact definition of the scienter requirement . . . ."); United States v. Jain, 93 F.3d 436 (8th Cir. 1996), *cert. denied*, 117 S. Ct. 2452 (1997) (upholding jury instruction that willfulness" should be found if the defendant acted "unjustifiably and wrongfully" in taking fees for referring patients to a psychiatric hospital if he knew that his conduct should be so characterized); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998) (defining knowingly as an act "done voluntarily and intentionally, not because of mistake or accident," an "willfully" as an act "committed voluntarily and purposely with the specific intent to do something the law forbids; that is to say, with bad purpose either to disobey or disregard the law); United States v. Starks, 157 F.3d 833 (11th Cir. 1998) (upholding the *Davis* definition of "willfully").

invalidated marketing arrangements because such arrangements are illegal under the statute. For example, one court invalidated a marketing agreement between Quantum Health Services, Inc. ("Quantum"), a supplier of durable medical equipment, and Nursing Home Consultants, Inc. ("NHC"), a company that marketed medical supplies to nursing home patients.[17] Under that marketing agreement, NHC was to identify Medicare recipients who needed medical supplies and put those recipients in touch with Quantum. Quantum would then sell its products directly to the nursing homes (on behalf of the patients). NHC would, in turn, receive compensation determined upon a per-item basis, derived from the number of units Quantum sold to nursing home residents identified by NHC. Allegedly, Quantum shipped goods to the nursing homes through affiliates that were not parties to the marketing agreement in an attempt to circumvent its payment obligations, and NHC sued. Quantum countered that the marketing agreement itself was illegal and that the contract was, therefore, unenforceable. The court agreed, concluding that the contract violated the anti-kickback statute:

> [t]he Marketing Agreement, by virtue of its compensation scheme, falls directly within the class of transactional relationships prohibited by [the federal anti-kickback statute]. NHC was paid for referring persons who needed Medicare-covered supplies to Quantum, who in turn sold them those supplies (via their nursing homes). . . .[18]

In the alternative, the court stated that the relationship between Quantum and NHC could be characterized as a payment for recommending to Medicare recipients that they purchase supplies from Quantum in violation of the anti-kickback statute.[19] In addition, the court noted that the marketing agreement did not meet applicable safe harbor criteria. Thus, the court concluded: "[n]o matter how you slice it, the Marketing Agreement violates [the federal anti-kickback statute], and accordingly the subject matter of that agreement . . . is prohibited by that statute, as is the performance of that agreement."[20]

In another case, *Modern Medical Laboratories*, a court reviewed a breach of contract action related to an agreement to market, manage and operate medical laboratories.[21] In this instance, SmithKline argued, and the court

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[17] Armstrong Health Care, Inc. v. Nurs. Home Consultants, Inc., 926 F. Supp. 835 (E.D. Ark. 1996)

[18] *Id.* at 842-43.

[19] *Id.* at 843

[20] *Id.*

[21] Modern Medical Laboratories, Inc. v. SmithKline Beecham Clinical Laboratories, Inc., No. 92 C 5302, 1994 WL 449281 (N.D. Ill. Aug. 17, 1994),

agreed, that the contract was illegal because it involved arranging for the purchasing of a Medicaid-reimbursable service. The court stated: "As we read this subsection, it criminalizes broker-style arrangements whereby one entity receives remuneration for placing business with another entity."[22] The court noted that it was irrelevant that a physician made the initial decision to purchase certain testing services. Rather, the court indicated that the federal anti-kickback statute reaches activity whereby one entity receives remuneration for essentially taking an "order" and arranging for another entity to perform the work.[23] Similarly, a Florida court invalidated a consulting agreement involving the marketing of durable medical equipment to physicians, nursing homes, retirement homes, and individual patients because the agreement involved payment of a percentage of sales.[24] In conclusion, there is ample court authority holding that a simple percentage-based marketing arrangement may, in some instances, violate the anti-kickback statute.

IV. OIG AUTHORITY

A. *Comments in Preamble to Safe Harbors*

The OIG has long held that payments of marketing commissions may violate the anti-kickback statute:

> In response to the October 21, 1987, request for comments, many commentators have suggested that we broaden the [employment] exemption to apply to independent contractors paid on a commission basis. We have declined to adopt this approach because we are aware of many abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision. We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts.[25]

The OIG consistently maintained its opposition to expanding the employee safe harbor to include independent contractors paid on a

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[22] *Id.* at *3.

[23] *Id.*

[24] Medical Dev. Network, Inc., v. Prof. Respiratory Care/Home Medical Equip. Serv., Inc., 673 So.2d 565 (Fla. Dist. Ct. App. 1996).

[25] *See* 54 Fed. Reg. 3088, 3089 (Jan. 23, 1989).

commission basis. In comments to the preamble of the final safe harbors issued in 1991, the OIG stated:

> We continue to reject this approach because of the existence of widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control. Although two commenters asserted that they could achieve appropriate supervision and control of independent contractors by including restrictive terms in the contract, we cannot expand this provision to cover such relationships unless we can predict with reasonable certainty that they will not be abusive. We are confident that the employer-employee relationship is unlikely to be abusive, in part because the employer is generally fully liable for the actions of its employees and is therefore more motivated to supervise and control them.[26]

Significantly, however, in response to other comments requesting that the OIG protect marketing and advertising activities because such activities promote competition or do not violate the statute, the OIG noted that many marketing and advertising activities may involve at least technical violations of the anti-kickback statute.[27] The OIG then stated that many of these marketing and advertising activities should not be subject to prosecution because they are passive in nature and do not involve direct contact with program beneficiaries, or because the individual or entity involved in these promotions is not involved in the delivery of health care.[28]

B. OIG Advisory Opinions

Another source of guidance with respect to the applicability of the anti-kickback statute to a particular arrangement is the OIG advisory opinion process. In order to assist health care providers in structuring their relationships, Congress, in 1996, passed legislation directing the OIG to issue written advisory opinions regarding, among other things, whether certain conduct (including but not limited to the anti-kickback statute) could result in the imposition of civil or criminal penalties or exclusion from participation in federal health care programs.[29] Each advisory opinion is binding upon the

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[26] 56 Fed. Reg. 35,952, 35,981 (July 29, 1991).

[27] *Id.* at 35,974.

[28] *Id.*

[29] Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 205 (codified at 42 U.S.C. § 1320a-7d (1999)).

Department of Health and Human Services and the parties thereto with respect to the issues that are addressed in that opinion.[30] Thus, the purpose of the advisory opinion process is to allow the agency with expertise on health care fraud matters (the OIG) to immunize business arrangements from prosecution and to promote consistency and uniformity in the interpretation of the federal health care anti-fraud provisions contained in the Social Security Act.

To date, the OIG has issued several advisory opinions discussing percentage-based marketing arrangements.[31] The first of these, OIG Advisory Opinion 98-1, dealt with a consignment arrangement to market durable medical equipment and the potential violation of several other laws, including prohibitions upon submitting claims substantially in excess of usual charges, false claims, and provision of items or services not provided as claimed.[32] Without repeating the complex facts underlying this opinion in detail, the OIG focused on three factors in determining that the percentage compensation arrangement is problematic:

(1) The arrangement included significant financial incentives that increase the risk of abusive marketing and billing practices. Here, the OIG noted that the marketing company would be billing and submitting claims to the Medicare program.

(2) The marketing company would have direct contact with referral sources and possibly Medicare patients.

(3) The arrangement contained no safeguards against fraud and abuse. The OIG was especially suspect of this arrangement because a recent OIG report had concluded that orthotics were subject to significant abuse.[33] In this instance, the OIG noted that the orthotics in question were paid for by patients and third party payors, rather than by the physicians who would order and dispense them.

The OIG concluded that the arrangement posed "an unacceptable risk" of fraud and abuse so as to preclude a favorable advisory opinion.

A second OIG advisory opinion regarding an arrangement between a physician practice management company ("PPMC") and a physician further

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30 42 U.S.C. § 1320a-7d(b)(4)(A) (1999).

31 This article was drafted in December, 1998. Although the author has made sporadic attempts to update it since then, time constraints preclude a more complete discussion of the relevant advisory opinions issued since that date.

32 OIG Advisory Opinion 98-1 (March 19, 1998).

33 *See* OIG Report, Medicare Orthotics, (OIE-02-95-00380, October, 1997).

identified issues of concern with respect to marketing activities.[34] In this arrangement, the PPMC would engage in direct marketing services and would set up a network to which the physician would be required to refer his patients. In return, the PPMC would receive a percentage of the physician's net revenues.

In analyzing the arrangement, the OIG reiterated its position that percentage-based compensation may implicate the anti-kickback statute. The OIG then pronounced the same three concerns it raised in Advisory Opinion 98-1 (that the arrangement may include financial incentives to increase referrals, there was a lack of safeguards against overutilization, and financial incentives that might increase the risk of abusive billing practices). However, based upon the discussion contained in Advisory Opinion 98-4, it is evident that the requestor did not supply the OIG with detailed information concerning the type of marketing activities that the PPMC would undertake. As such, it is not surprising that the OIG rendered a negative decision, because in the absence of materials justifying the relationship, the OIG had no basis to assume that the marketing activities would be conducted in a manner that would not be detrimental to the federal health care programs.

In an subsequent advisory opinion request in which the OIG was provided with substantially more information, the OIG did issue an opinion that provides important guidance with respect to how percentage-based compensation arrangements may be structured in order to avoid prosecution under the anti-kickback statute.[35] This opinion is significant because it indicates that the OIG would not seek to prosecute or impose other penalties upon a manufacturer and a sales agent who entered into a percentage-based independent contractor relationship. Under the arrangement, a manufacturer of disposable medical supplies agreed to pay the sales agent a commission of 1% to 1.25% of invoiced amounts to six potential purchasers. The sales agent's representation of the manufacturer was limited to submitting bids and negotiating contracts with the purchasers and making routine follow-up calls to resolve questions and to report and reconcile group purchasing organization fees and discounts.

In analyzing the arrangement, the OIG looked at six specific "suspect characteristics" identified as being associated with an increased potential for program abuse, particularly overutilization and excessive program costs. These factors were:

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[34] OIG Advisory Opinion 98-4 (April 15, 1998).

[35] OIG Advisory Opinion 98-10 (August 31, 1998).

1. Compensation based upon percentage of sales;
2. Direct billing of a Federal health care program by the seller for the item or service sold by the sales agent;
3. Direct contact between the sales agent and physicians in a position to order items or services that are paid for by a federal health care program;
4. Direct contact between the sales agent and Federal health care program beneficiaries;
5. Use of sales agents who are health care professionals or persons who are in a similar position to exert undue influence on purchasers or patients; or
6. Marketing of items or services that are separately reimbursable by a Federal health care program, whether on the basis of charges or costs.

In concluding that the arrangement would not be subject to prosecution, the OIG noted that although the agreement involved percentage-based compensation, none of the other factors triggering increased scrutiny was present.

V. STRUCTURING MARKETING ARRANGEMENTS

Based upon the authority referenced above, there is ample reason for providers to be cautious in structuring their marketing arrangements. Inasmuch as a marketing relationship, by its very nature, involves the generation of business for a health care provider, any payments made or received under such an arrangement may well constitute a "knowing" and "willful" violation of the anti-kickback statute. Moreover, civil courts have interpreted the statute broadly for purposes of invalidating contractual arrangements, and civil courts do not appear to recognize the OIG's distinction between "technical" violations of the anti-kickback statute and more flagrant violations that will be subject to prosecution.[36] Finally, providers should realize that their activities may be subject to prosecution under the statute even if they do not increase costs to the Medicare or Medicaid programs.[37]

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[36] *See* 56 Fed. Reg. 35,954 (setting forth three possible scenarios for failure to comply with a safe harbor: an arrangement may not fall within the statute, it may be a clear statutory violation, and it may "violate the statute in a less serious manner" that may be subject to prosecution based upon the many factors that are part of the decision-making process regarding case selection and prosecution).

[37] *See id.* quoting U.S. v. Ruttenberg, 625 F.2d 173, 177 n.9 (7th Cir. 1980).

A. Employment

As implied by the OIG's 1989 comments to the proposed safe harbor regulations, the easiest way for a health care provider to ensure that its marketing activities do not violate the anti-kickback statute is to have its own employees engage in marketing.[38] According to the OIG, employees engaged in marketing can be paid on a commission basis that takes into account the volume or value of referrals they generate. However, the employee safe harbor only protects relationships where the employee is "furnishing" an item or service payable in whole or in part under the Medicare or a State Medicaid program. Because marketing services are not reimbursed by Medicare or a State Medicaid program, a literal interpretation of the employee safe harbor would preclude payments to marketers from falling in that safe harbor.[39] It remains to be seen whether other courts will adopt this extremely rigid view of the scope of the employment safe harbor, especially since the OIG's own pronouncements with respect to the scope of that safe harbor support the conclusion that marketing employees can be paid on a commission basis.

B. Personal Services and Management Contracts

As a practical matter, many providers may find it difficult, if not impossible, to conduct their advertising, sales and marketing activities solely through employees because of the need for specialized data bases, mailing, televising, or otherwise disseminating information to prospective patients or referral sources. Moreover it may be difficult for providers to negotiate one-year contracts with fixed compensation that would qualify for protection under the personal services and management contracts safe harbor.[40]

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[38] The OIG has proposed a regulation that would enable it to prosecute "any transaction or other device entered into or employed for the purpose of appearing to fit within a safe harbor when the substance of the transaction or device is not accurately reflected in the form." 59 Fed. Reg. 37,202, 37,203. Thus, it is possible that even a bona fide employment relationship will not protect a marketing activity. However, in this instance, because there is also a statutory exception exempting payments to employees from the scope of the statute, it is the author's conclusion that the likelihood of the OIG prosecuting a bona fide employment relationship as a "sham" transaction is minimal.

[39] The *Starks* court, in dicta, expressed support for this narrow interpretation of the employee safe harbor.

[40] Readers would also be advised that the anti-kickback statute does not define the term "fair market value," the determination of which is a necessary step to receiving protection under the personal services and management contract safe harbor. One case, United States v. Lipkis, 770 F.2d 1447 (9th Cir. 1985), emphasized the importance of determining fair market value when assessing the legitimacy of payments between parties who are in a position to make referrals.

C. *Relationships that Do Not Qualify for Safe Harbor Protection*

Where a relationship does not qualify for a safe harbor (and, as indicated above, in the case of a "sham" relationship, even where the relationship does qualify for a safe harbor), providers will be forced to live with a degree of uncertainty as to whether they may face prosecution under the anti-kickback statute. In short, because the OIG has taken the position that *any* pure marketing relationship may constitute at least a technical violation of the anti-kickback statute, providers may be forced to accept the fact that any marketing activity may constitute a technical violation of the statute and focus upon reducing the risk of prosecution.[41] Stated otherwise, the ultimate goal of structuring any marketing relationship may be not so much to comply with the terms of the anti-kickback statute or a safe harbor as to prevent "abuses" (or perceived abuses) against federal health care programs.[42]

At the outset, providers should be aware that there may be a much different standard for the OIG to approve a relationship in an advisory opinion or to take civil or criminal action against the parties to the same arrangement. Stated otherwise, while the OIG is likely to render a favorable advisory opinion to a transaction that is "spotless" on paper, it is significantly less likely that the OIG will prosecute a marketing relationship unless the arrangement itself results in abusive practices directed toward federal health care programs. The remainder of this article will enumerate criteria that providers may wish to consider in structuring their marketing relationships under the anti-kickback statute.[43]

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[41] The author cautions that the scope of this statement is limited to marketing arrangements. Relationships that have a marketing component, but that are not "pure" marketing arrangements, might not violate the anti-kickback statute because the purpose of those arrangements may not be to induce referrals. *See, e.g.*, U.S. v. Greber, 760 F.2d 68, 71 (3d Cir. 1985); U.S. v. Bay State Ambulance, 874 F.2d 20, 30 (1st Cir. 1989) (both cases holding that payments violate the anti-kickback statute if "one purpose" is to induce referrals).

[42] On the other hand, the OIG itself has acknowledged that providers may legitimately conduct marketing activities. For example, in its Model Compliance Plan for Clinical Laboratories, the OIG stated that "[l]aboratory compliance plans should require honest, straightforward fully informative and non-deceptive marketing." Publication of the OIG Model Compliance Program Plan for Clinical Laboratory, 62 Fed. Reg. 9,435, 9,438 (1997). A revised version of this guidance entitled "Compliance Program Guidance for Clinical Laboratories" was published in Publication of OIG Compliance Program Guidance for Clinical Laboratories, 63 Fed. Reg. 45,076 (1998). Notwithstanding this tacit approval of marketing by a health care provider, it is clear that the analysis of almost any marketing activity will be subject to a "facts and circumstances" review.

[43] Although some of these criteria apply only to relationships that do not qualify for safe harbor protection, as stated above, the anti-kickback statute does not protect the actual conduct of *any* marketing activities by marketers themselves.

In a solicitation for proposals for new safe harbors, the OIG has identified several potentially relevant factors to consider when assessing a particular practice.[44] Although these factors apply only to proposals for new safe harbors, it is likely that they will also play a role in determining whether a particular arrangement that does not qualify for safe harbor protection will be prosecuted. The factors enumerated by the OIG in its solicitation include:

- The impact on access to health care services;
- The impact on quality of health care services;
- The impact upon competition among health care providers;
- The cost to federal health care programs;
- The potential for overutilization of health care services;
- The ability of health care facilities to provide services in medically underserved areas or to medically underserved populations; and
- The potential financial benefits to health care professionals or providers that may vary based upon their prescribing and referral decisions.

The OIG's analysis of a particular activity will typically, if indirectly, turn upon these criteria, and providers would be well-advised to consider these factors in determining how to conduct their marketing activities. Given the OIG's long-standing suspicions of marketing activities and relationships, providers should be careful to weigh each of these factors equally.[45]

The OIG has never published any statement reflecting a desire to end all marketing practices. However, the OIG has repeatedly expressed concerns related to the vulnerability of elderly patients to a variety of marketing practices and the fact that, because of asymmetry of information, health care providers may be able to exert substantial influence over the purchasing decisions of their patients.[46] Thus, one consideration is the nature of the contact between a marketer and a patient. For example, passive advertising may be viewed as less intrusive than door-to-door marketing, telephone solicitations, and targeted direct mail. Similarly, marketing activities by a

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[44] Solicitation of New Safe Harbors and Modifcations to Existing Safe Harbors, 61 Fed. Reg. 69,060, 69,061 (1996).

[45] For example, the OIG has specifically stated that increased cost to the Medicare and Medicaid programs and harm to beneficiaries are not the only criteria that the OIG will look at in determining whether a particular business arrangement is abusive. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,954 (1991) (to be codified at 42 C.F.R. pt. 1001).

[46] Of course, the OIG has also expressed concerns regarding blatantly fraudulent activity undertaken by marketers.

health care provider or other persons in a position of trust may be more likely to be subject to scrutiny. Activities that target senior citizens, Medicaid beneficiaries, or other "vulnerable" audiences may be more "at risk" than broad-based marketing activities. On the other hand, informational marketing efforts directed at health care professionals may be less risky, because by virtue of their training and experience, such professionals, on the other hand, can be expected to exercise independent judgment. Finally, marketing arrangements that relate to an item or service that has undergone a rapid increase in utilization or been subject to past abuses should be reviewed with extra caution.

Another factor that the OIG is likely to consider in deciding whether to prosecute any marketing relationship is billing. As the OIG indicated in Advisory Opinion 98-4, where marketing functions are delegated along with billing functions, the possibilities for fraud and abuse increase because the marketer will be capable of inflating its compensation by submitting false claims. The OIG has repeatedly expressed concern over such billing relationships, and it can be expected to be suspicious of any relationship that does not qualify for safe harbor protection if it involves both a billing and marketing component.[47]

Providers should consider, as objectively as possible, whether the marketing activities will benefit patients by increasing awareness of a product or improving quality. While patients in certain markets may have a wide variety of choices of providers, in others, lack of information and competition may mean that patients are medically under served with regard to particular medical services. Without making blanket statements with regard to particular arrangements, examples of marketing or sales activities that may increase access and quality include educational seminars and materials provided to physicians and/or patients.[48] Similarly, medical compliance and follow-up activities that ensure a patient is complying with a plan of care may be viewed as beneficial, if properly conducted. These factors should be counterbalanced

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[47] *See, e.g.*, OIG Advisory Opinion 98-4; OIG Special Fraud Alert, "Fraud and Abuse in the Provision of Medical Supplies To Nursing Facilities," OIG 95-09, (August, 1995).

[48] The anti-kickback statute does not define the term "remuneration," and the OIG has refused to create a safe harbor for relationships involving a "de minumus" amount. *See* 56 Fed. Reg. at 35,954 (to be codified at 42 C.F.R. pt. 1001). However, the OIG has also indicated that giving certain gifts, such as free computers, may not violate the statute as long as those gifts do not have any "independent value" apart from the service that is being provided. Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,978. Similarly, although Section 231 of the Health Insurance Portability and Accountability Act of 1996 prohibits offering inducements to individuals that is "likely" to induce those individuals to order from a particular provider, there is an exception for incentives to promote the delivery of preventive care. 42 U.S.C. § 1320a-7a(i)(6)(c) (1999).

against the likelihood of overutilization and increased costs to federal health care programs.

Another issue for providers to consider is the financial benefits that may accrue to medical professionals depending upon their referring or prescribing patterns. Although most providers and manufacturers recognize that making overt payments to referral sources is illegal, they may wish to avoid marketing activities that may give providers information or incentives that may increase the likelihood of that provider engaging in improper conduct. For example, a manufacturer of surgical equipment should not market its goods by explaining that certain procedures are reimbursed at a higher rate than comparable, non-invasive procedures used to treat the same condition. Providers also should wish to avoid offering cash or other benefits in exchange for providing marketing or sales-oriented tasks such as "educational" or "counseling" activities with patients, or physician or patient outreach activities.[49]

The preamble to the final safe harbor regulations issued in 1991 clarifies that one issue the OIG has with independent contractor relationships is the degree of control that the contracting party will have over the marketer. In the preamble, the OIG indicated that a lack of supervision and control over independent-contractor marketers has resulted in "widespread abusive practices" because salespersons are not under adequate supervision and control.[50] Although two commenters asserted that they could achieve appropriate supervision and control of independent contractors by including restrictive terms in the contract, the OIG stated it could not expand the scope of the employment safe harbor unless it could "predict with reasonable certainty" that such a relationship would not be abusive.[51]

On its face, there appears to be a tension between the control that the OIG expects a health care provider to exercise over a marketer and the test for whether a relationship is an "independent contractor" relationship.[52] One possible response to this tension is to control the scope of activity delegated to the marketer. That is to say, a provider may choose to limit the marketer's activities in such a way as to minimize the chance of the marketer engaging in abusive activities. For example, to comply with Medicare restrictions against unsolicited telephone contacts, a supplier of durable medical equipment should limit any marketers with respect to such activities.[53] A

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49 *See* OIG Special Fraud Alert, "Prescription Drug Marketing Schemes," (August, 1994).

50 *See* 56 Fed. Reg. 35,981.

51 *Id.*

52 *See* Rev. Rul. 87-41, 1987-1 C.B. 296 (listing twenty factors as guides for determining whether sufficient control may be exercised by an employer to establish an employer-employee relationship).

53 *See* 42 U.S.C. § 1395m(a)(17) (1999).

provider may also restrict marketer's activities to comply with HIPAA restrictions upon beneficiary inducements.[54] Violations of any such limitations should, at the least, result in termination of the agreement, and providers may wish to consider financial penalties in addition.

Another way to limit the possibility of abuses occurring is the use of a compliance plan. The OIG now encourages all health care providers to create compliance plans for their employees and contractors, notwithstanding its previous assertions that employees are less likely to engage in fraudulent practices than independent contractors, and it has even gone so far as to publish "model" compliance plans targeted to specific industries.[55] In this regard, the OIG has expressed concerns with a variety of marketing-related practices, including "compensation programs that offer incentives for items as services ordered or revenue generated,"[56]and also expressed "concern" with percentage-based payments for sales and marketing personnel, irrespective of employment status. Although this again highlights percentage-based compensation as an area of concern, the model compliance plan does not go so far as to assert that such arrangements are *per se* illegal. To address this issue, with respect to marketers in independent contractor arrangements, health care providers may wish to demand a copy of the marketer's compliance plan (on a confidential basis, of course) and include a representation and warranty that the marketer will adhere to that plan.

VI. CONCLUSION

Unfortunately, there are no easy answers or "bright line" tests for health care providers to consider in structuring marketing relationships. In the current environment, with its focus upon reducing fraud as a means of decreasing health care costs, activities that are common in other industries may result in severe penalties, and other criminal sanctions. Providers that do not carefully consider the effects of the anti-kickback statute in structuring their marketing activities may find that they attract the wrong audience — federal regulators.

One of the apparent contradictions in health care marketing is that too much success may mean that the activity is problematic. Simply stated, providers must recognize that consumers of health care may be vulnerable and lack clear, complete information upon which the base health care decisions.

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[54] *See* Health Insurance Portability and Accountability Act of 1996, P.L. 104-191, § 231, codified at 42 U.S.C. § 1320a-7a(a)(5) (1999).

[55] *See e.g.*, 64 Fed.Reg. 36,360 (July 6, 1999) (compliance guidance for the durable medical equipment, prosthetics, orthotics, and supply industry).

[56] *Id.* at 36,374.

While unscrupulous providers may choose to use these factors for their own benefit, they may do so at the risk that the government's fraud-fighters will soon follow. However, even well-meaning providers should carefully review their activities in order to ensure that they do not run afoul of the prescriptions contained in the anti-kickback statute.