

[We have redacted specific information regarding the requester and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise specified by the requester.]

Issued: July 6, 1999

Posted: July 13, 1999

[name and address redacted]

Re: OIG Advisory Opinion No. 99-8

Dear [name redacted]:

We are writing in response to your request for an advisory opinion concerning Company A's arrangements with Company B, to facilitate a program of professional training for Company B's shoe sales associates and to arrange for personal appearances by podiatrists at Company B's shoe departments (collectively, the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), in the circumstances presented.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided, we conclude that the Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that, based on the totality of the facts and the safeguards present in the Arrangement, the Office of Inspector General ("OIG") will not subject Company A to sanctions for violations of the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Arrangement, as described and certified in your request letter and supplemental submissions.

This opinion may not be relied on by any persons other than Company A, the requester of this opinion, and is further qualified as set out in Part V below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Parties

Company A ("Company A") is a State D corporation engaged in the business of professional training and publishing. Company A is a wholly-owned subsidiary of Company C, another State D corporation. Company A is not related to any other party to, or participant in, the Arrangement.

Company B, ("Company B") is a major discount retailer and retailer of shoes. [Further identifying information redacted.]

B. The Arrangement

The Arrangement consists of two parts, each more fully described below. The first part, the "X Program", is a professional training program for Company B's shoe sales managers and associates. The second part, the "Y Network", is a program related to the X Program through which Company A assembles a network of podiatrists across the country to make scheduled appearances at Company B's shoe departments to advise and consult with Company B's customers and shoe sales associates.

1. The X Program

In May 1997, Company A entered into a pilot agreement (the "Initial Agreement") with Company B to test the X Program in selected stores. Under the Initial Agreement, Company A agreed, among other things, to do the following:

- License the trademark "X" to Company B on an exclusive basis.
- Develop "learning criteria" for shoe sales managers and associates in the areas of human anatomy of the foot and shoe design function.
- Create computer-based training modules for Company B's shoe sales managers and associates and develop achievement tests for persons who complete the training.
- Design lapel pins and certificates of merit to be manufactured or purchased by Company B and distributed to successfully trained employees.
- Arrange for certification of the training program by a nationally recognized podiatric organization.
- Design in-store posters to promote the program to customers and employees, to be printed, distributed, and placed by Company B.

For its part, Company B agreed to pay Company A certain fees for its services based upon the achievement of certain benchmarks in the development of the X Program and the number of stores participating. In addition, Company B committed to support the program through public relations and in-store awareness campaigns for both its employees and customers.

According to materials submitted by Company A, Company B anticipated that the X Program would better train shoe department sales associates, reduce sales associate turnover rates through greater employee job satisfaction, improve customer service, build consumer confidence, create consumer awareness, familiarize participating podiatrists with Company B's shoes, and ultimately increase shoe sales and profits.

The pilot program proved successful, with improved retention of shoe department sales associates and positive customer feedback. In July 1998, Company B and Company A entered into a second agreement (the "Implementing Agreement") to continue and expand the X Program at Company B stores on an exclusive basis for two years. In addition to its existing obligations under the Initial Agreement, Company A agreed to assist Company B with periodic upgrades of its computer training modules and, with Company B's "reasonable assistance", to create a "referral service" of podiatrists located near the participating Company B stores (the Y Network, described below).⁽¹⁾

Under the Implementing Agreement, Company B agreed to pay Company A an exclusive licensing fee of \$[redacted] per year and a program fee of \$[redacted] per year, subject to certain adjustments tied to reductions in turnover of sales associates. Company A has represented that all fees paid, or to be paid, by Company B under the Initial and Implementing Agreements represent fair market value for the services rendered or to be rendered by Company A.⁽²⁾

2. The Y Network

The Y Network ("Y Network") is a program designed to create a pool of participating podiatrists to make scheduled appearances in Company B's shoe departments, as contemplated in the Implementing Agreement for the X Program. Participating podiatrists enter into one-year agreements with Company A pursuant to which they agree to provide one four-hour appearance each month at an assigned Company B location.⁽³⁾ The monthly in-store appearances are publicized by a plaque or posters in the store identifying the podiatrist and the date and time of his or her next appearance. In addition to the monthly in-store appearances, the podiatrist may participate from time to time in special events, including product knowledge demonstrations. During the scheduled appearances, the podiatrist answers questions from Company B's customers and employees regarding foot care and foot problems and conducts brief "foot screenings" in conjunction with answering questions.⁽⁴⁾ As an

additional service, some podiatrists provide free blood pressure screenings to Company B's customers.⁽⁵⁾

If a customer or employee asks a podiatrist about his or her private practice, the podiatrist is required to provide a written notice with explicit statements that Company B does not endorse the services of any individual participating podiatrist; that the podiatrist has an active license in good standing and has paid to participate in the Y Network; and that Company B's customers and employees are free to choose any provider of podiatric services. Participating podiatrists are not permitted to make on-the-spot appointments for their private practices, nor write prescriptions while on Company B's premises.

Podiatrists are not compensated for the in-store appearances. Materials marketing the Y Network to podiatrists promise the podiatrists high visibility, exposure to a large volume of customers, and the opportunity to be the exclusive, local foot care specialist at their Company B stores.

To participate in the Y Network, a podiatrist pays Company A a fixed annual fee, regardless of the size or volume of business of the store to which he or she is assigned.⁽⁶⁾ Company A has certified that this fee represents fair market value for the costs of operating the Y Network, including the costs of enrolling podiatrists, credentialing them, and assigning them to particular stores. To enroll as a Y Network podiatrist, a podiatrist must have an active license in good standing to practice podiatric medicine in the state in which the podiatrist practices and he or she must maintain professional malpractice insurance. Pursuant to the Implementing Agreement, Company B retained the right to disapprove any participating podiatrist for any lawful reason. The Implementing Agreement also provides that participating podiatrists must comply with written standards of conduct promulgated by Company B. In addition, podiatrists must also comply with the standards of conduct of the relevant state podiatric boards.

Podiatrists are assigned to Company B stores on a "first-come, first-served" basis. A second podiatrist may be assigned to a particular Company B store only with the consent of the first assigned podiatrist. Company A maintains a waiting list of podiatrists for whom there is currently no store available. Groups of podiatrists may share Company B locations for convenience, to spread the cost of the Y Network fee among several practitioners, and to ensure that a podiatrist is always available for the required in-store appearances.

In sum, the Arrangement consists of conjoined programs -- the X Program and the Y Network -- through which Company A provides Company B with professional training and in-store podiatrists and provides participating podiatrists with access to Company B's customers.

C. Federal Health Care Program Reimbursement

Some professional services provided by the podiatrists in their private practices are potentially reimbursable by Medicare, Medicaid, or other Federal health care programs.⁽⁷⁾ Additionally, some orthotics and other podiatric supplies and devices, as well as some drugs prescribed by podiatrists, may be available through Company B's pharmacy operations and may be reimbursable under Medicare, Medicaid, or other Federal health care program. Company A has certified that none of the services the podiatrists perform while at the Company B stores is reimbursable by any Federal health care program, and the podiatrists will not bill any Federal program for such services. Company A has further certified that neither Company B's pharmacies nor its pharmacy employees, contractors, vendors, or suppliers will promote, or participate in, the Arrangement and that there will be no direct or indirect connection between the Arrangement and Company B's pharmacy operations. Company A has also certified that none of the shoes or shoe products sold in the shoe departments of Company B's retail stores are reimbursable under any Federal health care program.

II. LAW

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any Federal health care program. See

section 1128B(b) of the Act. Specifically, the statute provides that:

"Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or 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."

Id. Thus, where remuneration is paid purposefully to induce referrals of items or services for which payment may be made by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. This Office may also initiate administrative proceedings to exclude persons from Federal and state health care programs or to impose civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.⁽⁸⁾

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The regulatory safe harbors potentially applicable to the Arrangement are the personal services and management contracts safe harbor, 42 C.F.R. § 1001.952(d), and the referral services safe harbor, 42 C.F.R. § 1001.952(f). In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the compensation paid for services be set at fair market value in an arms-length transaction, 42 C.F.R. § 1001.952(d)(5); the referral services safe harbor requires that the referral service be open to anyone who meets the qualifications for participation and that payments made by participants be based only on the costs of operating the referral service, 42 C.F.R. §§ 1001.952(f)(1) & (2).

III. ANALYSIS

The threshold inquiry under the anti-kickback statute is whether the Arrangement involves any transfer of remuneration to a person or entity who refers Federal health care program business or arranges for or recommends the purchase, lease, or ordering of items or services reimbursable by a Federal health care program. Company A claims that the promotional activities contemplated under the Arrangement do not involve "arranging for or recommending" within the meaning of the statute, and that, in any event, no economic benefit flows from the podiatrists to Company B for any referrals as a result of the interposition of Company A as an unrelated third-party intermediary. For the reasons set forth below, we disagree.

The promotional activities conducted by Company A and Company B come within the plain language of the statute, which prohibits payments to a person to "arrange for or recommend" the purchasing or ordering of a good or service payable by a Federal health care program. Not only are Company A and Company B providing in-store posters and "awareness" campaigns, they are also orchestrating an opportunity for the podiatrists to market their services personally -- and exclusively -- to potential patients. The in-store signs, special promotions, and authorized presence of the podiatrists in Company B's shoe departments, coupled with Company B's retained

right to disapprove any participating podiatrist, amount to an implied recommendation of the podiatrists by Company B, notwithstanding the written disclaimers the podiatrists are required to distribute to customers. Some of those customers will be Federal health care program beneficiaries, and some of the services subsequently provided by the podiatrists to those customers in the podiatrists' private practice may be reimbursable under a Federal health care program.

Having established an implied recommendation, we also think that both Company A and Company B receive an economic benefit (or "remuneration") in exchange for these promotional activities, since the podiatrists receive no monetary compensation for their in-store appearances each month.⁽⁹⁾ These free services benefit both Company A, which otherwise has a contractual obligation to Company B to provide the podiatrists, and Company B, which desires the podiatrists' monthly in-store appearances for its own purposes. The OIG's position on the provision of free or below market value goods or services to potential referral sources is longstanding and clear: the provision of free goods or services to an actual or potential referral source may violate the anti-kickback statute, depending on the circumstances. For example, the preamble to the 1991 safe harbor regulations explains that giving free goods that have an independent value to a physician may violate the anti-kickback statute. See 56 Fed. Reg. 35978 (July 29, 1991); see also Special Fraud Alert, 59 Fed. Reg. 65372, 65377 (Dec. 19, 1994); OIG Advisory Opinion 98-16. This analysis generally applies to the provision of any free or below market value goods or services to actual or potential referral sources. If the requisite intent to induce or reward referrals of Federal health care program business is present, the anti-kickback statute is violated.

The interposition of Company A as an intermediary between Company B and the podiatrists does not vitiate our anti-kickback concerns. Through its contractual arrangements with Company B and the participating podiatrists, Company A is in a position to channel "recommendations" from Company B to the podiatrists and "remuneration" from the podiatrists to Company B. Moreover, in some circumstances this type of arrangement could pose a risk that the intermediary would be buying one party's recommendations and reselling them to another party. For example, Company A could accomplish this result if it were to "purchase" Company B's recommendations by selling its X Program services to Company B for less than fair market value (i.e., giving "remuneration") and then "sell" the recommendations to the participating podiatrists by providing its Y Network services at more than fair market value (i.e., receiving "remuneration"). However, as noted above, Company A has certified that its fees from both Company B and the podiatrists are at fair market value.

Neither of the potentially applicable safe harbors protects the Arrangement. The personal services contracts safe harbor does not apply, because the podiatrists are not compensated for the free services they render, apart from the opportunity to generate business. See 42 C.F.R. § 1001.952(d)(5). The referral services safe harbor is also inapplicable, because the exclusive location feature of the Y Network excludes some podiatrists from participating and because Company A intends to operate the Y Network at a profit. See 42 C.F.R. §§ 1001.952(f)(1) & (2).

In these circumstances, we conclude that the Arrangement potentially violates the anti-kickback statute insofar as the podiatrists may be giving something of value to Company B and Company A in exchange for promotional activities that rise to the level of "arranging for or recommending" within the meaning of the statute.

Notwithstanding, in the particular factual circumstances presented and based on the totality of the following factors, we conclude that for purposes of the anti-kickback statute the Arrangement poses a low risk of fraud and abuse and contains safeguards that further reduce that risk for the reasons set forth below.

The risk of program or patient abuse from the Arrangement is relatively low, since Company B and Company A have a limited ability to influence a significant flow of Federal health care program business to the podiatrists. In evaluating the risks posed by arrangements involving direct or indirect promotional or marketing activity involving potential patients, like Company B's constructive endorsement of the participating podiatrists, we look to a number of factors, including, but not limited to, the following:

- **The identity of the party engaged in the marketing or promotional activity and the party's relationship with its audience.** For example, relevant inquiries may include whether the party is involved

in the delivery of health care (e.g., a doctor, a nurse, a home health aide, or the like) and whether the party is otherwise in a position to exert undue influence on potential purchasers or patients.

- **The nature of the marketing or promotional activity.** One relevant factor is whether and to what degree the activity may be coercive, or perceived to be coercive, by the party to whom the activity is directed. For example, door-to-door marketing, telephone solicitations, and direct mailings are more intrusive, and typically pose a greater potential for abuse, than truthful passive advertising in general circulation newspapers or on television.
- **The item or service being promoted or marketed.** Pertinent here, for example, is whether the marketing or promotion identifies specific items or services or whether it consists of more general descriptions of providers or suppliers (e.g., "image" advertising). Another consideration is whether the item or service marketed or promoted is one for which there is a likelihood of overutilization based on the historical experience of the Federal health care programs, reimbursement methodology, or other reason.
- **The target audience.** Relevant aspects include whether the activity is specifically directed at senior citizens, Medicaid beneficiaries, or other particularly vulnerable populations. The more focused the marketing or promotional activity is on persons likely to be Federal health care program beneficiaries, the greater the risk to the Federal health care programs and their beneficiaries.

We emphasize that these factors are not indicative or necessarily probative of whether a practice, in fact, actually violates the anti-kickback statute. Rather, we weigh these factors, as well as other relevant concerns, in assessing the level of risk presented by promotional and marketing activity. These factors are not exclusive and the presence or absence of any one factor is not determinative of whether, in our discretion, we would subject parties engaged in marketing or promotional activity to sanctions for violating the anti-kickback statute.

In the instant case, consideration of these factors, coupled with the safeguards described below, suggests that the risk posed by the Arrangement is low. Neither Company B's shoe departments⁽¹⁰⁾ nor Company A is involved in the delivery of health care. Company B's shoe departments sell no products and provide no services reimbursable by any Federal health care program. Neither Company B, a diversified discount retailer serving a broad spectrum of the general public, nor Company A, a professional training and publishing company, has any special health care relationship with Company B's shoe department customers.⁽¹¹⁾ While participating podiatrists may benefit from the halo effect attributable to their association with Company B, the Arrangement involves no explicit arranging for or recommending of any good, facility, service, or item payable by a Federal health care program by either Company B or Company A. No specific podiatric services are promoted or marketed. Finally, while it involves direct patient contact, the Arrangement is not targeted at Federal health care program beneficiaries, and neither Company B nor Company A has control over the prospective patient mix of the shoe department customers.

Three safeguards provide additional protection against fraud and abuse. First, the fees paid by the podiatrists to Company A do not vary based on the actual or anticipated volume or value of referrals. Podiatrists each pay the same fixed fee regardless of the size or volume of business of the stores to which they are assigned. After an initial six-month trial period, podiatrists must commit to a second six-month term and then to one-year terms thereafter, during which terms they are obligated to provide in-store appearances, even if no referrals result.

Second, the podiatrists provide Company B's customers and employees who inquire about their private practices with written disclosures indicating that Company B does not endorse the in-store podiatrist and informing them of their freedom of choice. While we do not believe that such disclosures offer sufficient protection from program abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.

Third, the risk of cross-referrals to Company B's pharmacy is minimal. Neither Company B's pharmacies nor its pharmacy employees, contractors, vendors, or suppliers will promote, or participate in, the Arrangement, and there will be no direct or indirect connection between the Arrangement and Company B's pharmacy operations. The participating podiatrists are barred from writing prescriptions while on Company B's premises.

As indicated above, our determination not to impose sanctions in these circumstances is attributable to the entirety of the facts of the Arrangement, including, but not limited to, the identities of the parties and the level of promotional activities. We would likely reach a different conclusion if the Arrangement involved a different setting or different parties, for example, if the participating podiatrists were providing free services (whether directly or facilitated by an intermediary) to nursing homes, assisted living facilities, senior centers, community clinics, physicians' offices, hospitals, home health agencies, or other more traditional sources of referrals of Federal health care business or places where Federal health care program beneficiaries typically seek health care or personal care services. Likewise, we would find suspect a similar arrangement involving Company B's pharmacy departments and physician in-store appearances or one involving an express Company B endorsement of a health care provider.

IV. CONCLUSION

Based on the information provided, we conclude that the Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that, based on the totality of the facts and the safeguards present in the Arrangement, the OIG will not subject Company A to sanctions for violations of the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Arrangement, as described and certified in the request letter and supplemental submissions.

V. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company A, the requester of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requester to this opinion.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement.
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the requester with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, the fees paid under the Arrangement are fair market value, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the requester with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, where the fees paid under the Arrangement were at fair market value, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton

Chief Counsel to the Inspector General

FOOTNOTES:

1. The concept of a podiatrist "referral service" first appeared in the Initial Agreement, but no such referral service was created pursuant to that agreement.
2. We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). For purposes of this advisory opinion, we rely on the requesting party's certification of fair market value. If the fees paid are not fair market value, this opinion is without force and effect.
3. When first entering the Y Network, podiatrists enroll for an initial six month trial period, followed by an additional six month period. The trial period allows the podiatrists to test the program and permits Company A to comply with certain franchising regulations.
4. According to Company A, a "foot screening" is understood by the podiatric medical community as a brief look at the feet, not an examination to evaluate a patient's need for medical treatment.
5. Company A has certified that these blood pressure screenings are the only additional services provided by the podiatrists.
6. Podiatrists pay \$[redacted] for an initial six month trial period. For purposes of this advisory opinion, we rely on Company A's certification that the fees charged to podiatrists represent fair market value for services provided. If the fees paid are not fair market value, this opinion is without force and effect.
7. Routine foot care services are generally excluded from coverage under Part A and Part B of Medicare, as are most orthopedic shoes and other supportive devices. See 42 U.S.C. §§ 1395y(a)(8) & (13).
8. Because both the criminal and administrative sanctions related to the anti-kickback implications of the Proposed Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.
9. In addition, Company A collects fees from the podiatrists to participate in the Y Network. Company A has certified that these fees are fair market value for services rendered by Company A. However, this certification does not account for the value of the podiatrists' free services.
10. Company B's pharmacy operations are specifically excluded from any involvement in the Arrangement.
11. Unless, of course, the shoe department customers are also customers of the pharmacy or other department selling health care or personal care items or services.