

[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requester.]

Issued: October 25, 1999

Posted: November 1, 1999

[Names and Addresses redacted]

Re: OIG Advisory Opinion No. 99-10

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a corporate sponsorship program between Drug Company A ("Company A") and Charity B ("Charity B") (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement constitutes grounds for sanctions under the anti-kickback statute, section 1128B(b) of the Social Security Act (the "Act"), or under the civil monetary penalty provision for inducements to beneficiaries, section 1128A(a)(5) of 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 (i) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that the Office of Inspector General ("OIG") will not subject Company A or Charity B to sanctions arising under the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Proposed Arrangement, as described and certified in the request letter and supplemental submissions; and (ii) the OIG will not subject Company A or Charity B to sanctions under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement.

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

I. FACTUAL BACKGROUND

A. The Parties

Company A is a licensed pharmacy that dispenses respiratory drugs via mail order to patients in State X and other states. Respiratory drugs, and the nebulizers used to inhale them, are provided pursuant to a prescription from a patient's physician. Patients usually obtain the drugs from a pharmacy and the nebulizer from a durable medical equipment ("DME") supplier. Company A's business typically comes from referrals from physicians and DME suppliers. Many customers are covered by Medicare, Medicaid, or other Federal health care program.

Charity B is a 501(c)(3) charitable organization in State X formed to conduct educational and public awareness campaigns about lung diseases and the hazards of smoking and to promote activities that lead to healthy lungs. Charity B is a state constituent of the American Lung Association. Charity B does not provide any DME or prescribe any drugs, make any referrals to particular providers of health care services (including pharmacies), or express any preferences regarding any providers. Charity B receives financial support from individuals and corporations. Aggregate annual donations typically fluctuate between \$[x] and \$[y] million. No shareholders, officers, directors, or employees of Company A serve on Charity B's board of directors or on any other Charity B decision-making body.

B. The Proposed Arrangement

Company A and Charity B wish to enter into an arrangement pursuant to which Company A will make charitable donations to Charity B, and Charity B will allow Company A to use its name, logo, and other proprietary symbols and phrases (collectively, for purposes of this opinion, "Charity B's marks") for certain limited promotional activities (the "Proposed Arrangement"). There will be no other business arrangements between Company A and Charity B. Company A will not offer patients rebates or discounts on nebulizer drugs in connection with the Proposed Arrangement.

Under the Proposed Arrangement, Company A would donate a fixed sum to Charity B for each nebulizer drug prescription Company A fills for patients residing in State X. The sum would not exceed ten dollars per prescription shipment. In order to calculate the aggregate donation, Company A would track prescriptions by the state in which the patient resides, but not by referral source or patient name. The Proposed Arrangement would be an exclusive arrangement; neither Company A nor Charity B would enter into a similar arrangement with any other party.

Charity B will permit Company A to use Charity B's marks solely in advertising and promotional materials that generally identify, describe, or portray the Proposed Arrangement or Charity B's charitable activities. The thrust of any advertising will be the promotion of Charity B's charitable activities and Company A's financial support of those activities. For example, promotional material may describe Charity B's children's programs and may indicate that Company A is providing financial support for those activities.⁽¹⁾ Promotional material under the Proposed Arrangement will not refer to Company A's products or services, and Charity B's marks will not be used in, or in connection with, any advertising for Company A's products or services. Advertisements will not be placed or distributed so as to suggest Charity B's endorsement of any specific Company A product or service (e.g., advertisements about the Proposed Arrangement will not be placed alongside or in the vicinity of Company A product advertisements; brochures about the Proposed Arrangement will not be accompanied by advertisements for specific Company A products or services).

The majority of Company A advertising of the Proposed Arrangement will be placed in regional trade publications directed at DME companies, physicians, respiratory therapists, and other health care professionals who have direct contact with patients using nebulizer drugs. None of these health care professionals will receive any financial incentive to induce referrals as a result of the Proposed Arrangement.⁽²⁾ Company A may also send brochures explaining the Proposed Arrangement to its existing patient customers, as well as DME suppliers, physicians, respiratory therapists, and other appropriate health care professionals. Company A will not send brochures or other marketing materials to prospective patient customers.

All advertising or other materials that use Charity B's marks will be subject to Charity B's review and approval. Charity B has represented that it will not permit Company A to use Charity B's marks in any way that would constitute an endorsement of Company A's products or services. Charity B may itself promote the Proposed Arrangement through its newsletter or in a separate letter from Charity B's president to its membership. Neither the newsletter nor the president's letter will describe, recommend, or endorse any particular Company A product or service.

Company A and Charity B have certified that all advertising and promotional activity under the Proposed Arrangement will comply with all applicable Federal and state laws and regulations, including, but not limited to, compliance with consumer laws prohibiting false advertising, unfair and/or deceptive advertising, and consumer fraud.⁽³⁾

Charity B would treat Company A's donations as unrestricted general corporate donations. The proceeds would go into Charity B's general fund to be used at the sole discretion of Charity B's board of directors. Although the funds are unrestricted and may be used as the board sees fit, the parties anticipate that Company A's funds would be used for three Charity B projects that serve children with asthma: a free summer camp with special asthma-related activities, an asthma screening program to identify children at risk for asthma, and a school-based educational program to teach children to manage their asthma. The funding and operation of these programs,

including the selection of participating children, is wholly the responsibility of Charity B, without any participation by Company A. Company A is not informed of the identity of program participants. While the scope and intensity of program services will be enhanced by Company A's donations, none of the Charity B programs will be dependent on them. At ten dollars per prescription shipment, Company A estimates that its annual donations to Charity B will be in the range of \$[c] to [d], amounting to approximately [less than 9%] of Charity B's total revenue from grants and donations.

C. Federal Reimbursement

Because they are considered supplies necessary for the proper use of a nebulizer, respiratory drugs are covered by Medicare Part B's DME, prosthetics, orthotics, and supplies ("DMEPOS") benefit. For covered nebulizer drugs, Medicare pays the dispensing pharmacy 80% of the lesser of (i) the actual charge or (ii) the allowable 95% of the average wholesale price. See sections 1833(a)(1) and 1842(o) of the Act. The beneficiary is responsible for paying the dispensing pharmacy the remaining 20% of the actual charge or 20% of the allowable 95% of the average wholesale price as a Medicare copayment.⁽⁴⁾ Company A has represented that the Medicare fee schedule is approximately eighty percent of Company A's usual and customary prices for respiratory drugs. Medicaid reimburses nebulizer drugs as a prescription drug benefit in accordance with the upper limits established by the Health Care Financing Administration. See 42 C.F.R. §§ 447.331-.334. Company A has certified that it will not seek to pass the costs of its donations through to any Federal health care program or beneficiary.

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.⁽⁵⁾

III. THE OIG WILL NOT SUBJECT THE REQUESTERS TO SANCTIONS UNDER SECTION 1128B(B) OF THE ACT

The threshold inquiry under the anti-kickback statute is whether the Proposed Arrangement involves any transfer of remuneration to a potential referral source, that is, to a person or entity that 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.

Payments by a health care entity to a charitable organization -- particularly one with a health care mission -- in exchange for the exclusive use of the charitable organization's name, logo, and other proprietary symbols and phrases for promotional purposes potentially implicate the plain language of the statute. Depending on the circumstances, the use of the name, logo, and other propriety material in promotional materials may amount to an express or implied recommendation by the charitable organization of the entity's products or services. To the extent such products or services are covered by the Federal health care programs, the statute may be implicated.

We have said previously that in evaluating the risks posed by arrangements involving direct or indirect promotional or marketing activity, we look at 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.
- The item or service being promoted or marketed.
- The nature of the marketing or promotional activity.
- The target audience.⁽⁶⁾

These factors are not indicative or necessarily probative of whether a practice, in fact, 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 other factors described below, suggests that the risk of unlawful kickbacks posed by the Proposed Arrangement is low.

We begin by recognizing that Charity B, like many nonprofit organizations, likely enjoys a high level of public recognition and trust, particularly among those in State X affected by respiratory diseases. Thus, a recommendation or endorsement by Charity B of Company A's products or services would probably carry great weight. However, where, as here, there is no recommendation or endorsement of any Company A product or service, Charity B's ability to influence referrals is more limited. In this regard, Company A and Charity B have certified that:

- Promotional activities will be limited to identifying, describing, or portraying generally the Proposed Arrangement and/or Charity B's charitable activities, without reference to any of Company A's products or services;
- Charity B's marks will not be used in, or in connection with, any Company A product or service advertising; and
- Advertisements will not be placed or distributed in such a way as to suggest Charity B's endorsement of any Company A product or service (e.g., advertisements about the Proposed Arrangement will not be placed alongside or in the vicinity of any Company A product advertisements; customer brochures about the Proposed Arrangement will not be accompanied by advertisements for specific Company A products or services).

Moreover, the promotional activities primarily involve print advertisements in trade publications aimed, not at prospective patient customers, but at a less vulnerable audience (i.e., health care professionals, such as DME suppliers, physicians, and respiratory therapists). There will be no direct contact with prospective Company A

patient customers. Direct contact with existing customers will be limited to brochures generally describing the Proposed Arrangement, without reference to specific Company A products or services.

Other aspects of the arrangement provide additional protection against fraud and abuse. No physician, DME supplier, respiratory therapist, or other health care professional in a position to refer patients to Company A will receive any remuneration under the Proposed Arrangement. Moreover, there is no risk that Company A will pass the costs of its donations on to Medicare through increased billings, as Company A's usual and customary charge is already substantially higher than the Medicare fee schedule.⁽⁷⁾ Nor will it pass those costs on to Medicaid, which pays under a fee schedule. In addition, Company A has certified that it will not seek to pass the costs of donations on to Federal beneficiaries by charging them in excess of the Federal program allowable amount.

Finally, we recognize that the Proposed Arrangement's fund-raising potential may significantly benefit children with asthma and others affected by respiratory diseases. In addition, the Proposed Arrangement may help Charity B publicize its programs to physicians and others in a position to refer children for Charity B services, while conserving scarce Charity B resources that might otherwise be spent on outreach efforts. Assuming that promotional activity under the Proposed Arrangement is truthful, non-deceptive, and not misleading, we think the Proposed Arrangement will generally benefit the public.

In sum, for the totality of the above reasons, we would not subject Company A or Charity B to sanctions arising under the anti-kickback statute in connection with the Proposed Arrangement.

IV. THE OIG WILL NOT SUBJECT THE REQUESTERS TO CIVIL MONETARY PENALTIES UNDER SECTION 1128A(a)(5) OF THE ACT

Section 1128A(a)(5) of the Act prohibits a person from offering or transferring remuneration to a beneficiary that such person knows or should know is likely to influence the beneficiary to order items or services from a particular provider or supplier for which payment may be made under the Medicare and Medicaid programs.

Company A and Charity B are concerned that the Proposed Arrangement may implicate section 1128A(a)(5), insofar as some beneficiaries might believe they stand a better chance of being able to participate in free Charity B programs (which are sometimes oversubscribed) if they purchase Company A's products. Even if this were likely, on the facts presented we do not believe the statute would be implicated. Any connection between participation in a Charity B program and the purchase of Company A's products would be wholly speculative. Thus, for the reasons stated here and above in Section III, the OIG will not subject Company A or Charity B to sanctions under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement.

V. CONCLUSION

Based on the information provided, we conclude that (i) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that the OIG will not subject Company A or Charity B to sanctions arising under the anti-kickback statute pursuant to sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Proposed Arrangement, as described and certified in the request letter and supplemental submissions; and (ii) the OIG will not subject Company A or Charity B to sanctions under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement.

VI. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to Company A, and Charity B, the requesters 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 in the first paragraph of this opinion. 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 Proposed 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 requesters with respect to any action that is part of the Proposed 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, and the Proposed 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 requesters 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, 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

FOTNOTES:

1. A prototype advertisement submitted with the advisory opinion request shows a photograph of children at summer camp with a caption stating that Company A is teaming up with Charity B to help asthmatic children attend Charity B's special summer camp and that a portion of the proceeds from the purchase of nebulizer drugs will be donated to Charity B to support the summer camp. The advertisement incorporates both Company A's and Charity B's logos. A preliminary version of the prototype included an instruction to readers (presumably physicians, DME suppliers, and respiratory therapists) to call Company A at a 1-800 number and "mention this offer." This element was subsequently deleted. Company A and Charity B have certified that advertisements under the Proposed Arrangement will not include any instructions to contact Company A or any suggestion that readers may receive a benefit if they contact Company A or if they recommend or purchase Company A's products or services. Advertisements may include instructions for contacting Charity B about Charity B's programs.

2. The requesters point out that some providers may benefit incidentally and indirectly if their pediatric patients partake of Charity B's asthma-related services supported by Company A and thus become better able to comply with their treatment plans.

3. Endorsements of commercial products by charitable organizations raise significant issues, not addressed here, of consumer and business law. This advisory opinion is limited to consideration of potential implications of the Proposed Arrangement under the anti-kickback statute and the section 1128A(a)(5) prohibition against inducements to beneficiaries. We express no opinion about the legality of the Proposed Arrangement under other laws.

4. If the provider does not accept assignment, there is no limiting charge; thus, beneficiaries may be charged amounts in excess of the Medicare allowable amount. Company A has certified that it will not require beneficiaries to pay more than 20% of the Medicare allowable amount.

5. 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.

6. See OIG Advisory Opinion 99-8 (July 6, 1999).

7. It would be inappropriate for Company A to offset its donations through higher billings to Medicare or other Federal programs. Thus, for example, if Company A's actual charges were lower than the Medicare fee schedule, Company A would be expected to bill Medicare the lower amount, without passing the cost of the donation to Charity B through to Medicare.