

[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: November 23, 1999

Posted: December 6, 1999

[name and address redacted]

Re: OIG Advisory Opinion No. 99-12

Dear [name redacted]:

We are writing in response to your request for an advisory opinion about a proposed marketing program involving the use of physician practices and health care clinics to distribute coupons redeemable by certain retailers (including grocery stores, pharmacies, and internet companies) for discounts on items or services that are not reimbursable by any Federal health care program (the "Proposed Arrangement"). Specifically, the question raised by your request is 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 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, based on the totality of the facts of the Proposed Arrangement (as described and certified in the request letter and supplemental submissions), the Proposed Arrangement does not implicate the anti-kickback statute and that 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 Proposed Arrangement, nor will the OIG impose civil monetary penalties on Company A in connection with the Proposed Arrangement for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act.

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

Company A ("Company A") is a closely-held State X corporation formed for the purpose of marketing products related and unrelated to the delivery of health care. Company A is not owned by, or affiliated with, any entity or person involved in the health care business. Company A has developed the Proposed Arrangement, a marketing program designed to increase customer traffic for participating retailers through the distribution of discount coupons by physicians and health care clinics.

Under the Proposed Arrangement, Company A will contract with retailers, including retail grocery stores, pharmacies, and internet companies (collectively, the "contracting retailers") to coordinate the printing and distribution of coupons redeemable for discounts at the retailers. Some of these contracting retailers will be involved in the delivery of health care items or services, and some people who receive the coupons will be Federal health care program beneficiaries who may purchase or order products or services from the contracting retailer that are reimbursable under a Federal health care program (e.g., prescription drugs payable by Medicaid). However, the coupons will not be valid for discounts on any items or services reimbursable by a Federal health care program, nor will their redemption be conditioned in any fashion on the purchase of any items or services reimbursable by a Federal health care program; rather, the coupons will offer discounts on non-prescription,

over-the-counter products. The coupons will be given to *all* individuals as they exit a clinic or physician's office, irrespective of their insurance coverage or whether they are likely to require covered items or services that the contracting retailer provides. Coupon recipients will be free to use or discard the coupon. The coupons are typically expected to be worth approximately \$[x] and will not exceed \$[y].

Company A has represented that the fee for its marketing services will be a fixed amount set in arms-length negotiations between Company A and each contracting retailer, will represent fair market value for Company A's marketing services,⁽¹⁾ and will not be determined in a manner that takes into account the volume or value of any Federally-reimbursable business generated (directly or indirectly) by the Proposed Arrangement. The fee paid by each contracting retailer will cover all of Company A's costs associated with performance of the contract to which the fee applies, including all costs associated with engaging physicians and health care clinics to distribute the coupons. Accordingly, Company A has a significant economic incentive to contain costs.

Taking into account the retailers' preferences as to markets and geographic location for the coupon distribution, Company A will enter into contracts with health care clinics and physician groups in the relevant locations to distribute the coupons. The length of the contracts will vary depending on the volume of coupons to be distributed by the particular clinic or physician group (in some cases the volume of coupons could be in the many thousands).

Company A has represented that the fee to be paid to the physicians and clinics will be fixed in arms-length transactions between Company A and the physicians and clinics, will be a few cents per coupon (usually less than [z] cents), will be set in advance (typically a fixed amount per coupon distributed), will represent fair market value for the distribution services, and will not be determined in a manner that takes into account the volume or value of any Federally-reimbursable business generated (directly or indirectly) by the Proposed Arrangement.

II. THE ANTI-KICKBACK STATUTE

The anti-kickback statute makes it a criminal offense knowingly and wilfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by the Federal health care programs. See section 1128B(b) of the Act. In relevant part for purposes of this advisory opinion, the statute prohibits the purposeful transfer of remuneration to a person or entity to induce the person or entity to arrange for or recommend the purchasing or ordering of a good or service payable by a Federal health care program. By its terms, the statute ascribes 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.⁽²⁾

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. The OIG 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.⁽³⁾

A. Analysis

Marketing by physicians or other health care professionals -- sometimes referred to as "white coat" marketing -- is closely scrutinized under the anti-kickback statute. Such parties are in an exceptional position of public trust and thus may exert undue influence when recommending health care-related items or services, especially when marketing to their patients. See, e.g., 56 Fed. Reg. 35974. Given the nature of the physician-patient relationship, when physicians market items and services to their patients, patients may have difficulty distinguishing between

the physician's professional medical advice on the one hand and a commercial sales pitch on the other.

Notwithstanding, we conclude that, on the facts presented, the Proposed Arrangement does not fall within the ambit of the anti-kickback statute, and even if it did, we would not subject Company A to OIG sanctions for violation of the anti-kickback statute. Simply put, on the facts presented, neither the contracting retailers nor Company A is paying the physicians and health care clinics to arrange for or recommend the purchase or order of items or services reimbursable by a Federal health care program.

Under the Proposed Arrangement, the physicians and clinics will be paid to distribute coupons that will entitle the holders to discounts on purchases of certain items that are not reimbursable by any Federal health care program at select retail stores.⁽⁴⁾ The coupons will not be tied directly or indirectly to the purchase or order of any items or services covered by a Federal health care program. The physicians and clinics will be required to distribute the coupons to *all* of their patients, without regard to their insurance coverage or the likelihood that they will require Federally-covered items or services provided by the retailer, or indeed will patronize the retailer at all. The contracting retailers will be businesses offering a wide variety of medical and non-medical items and services; none will be businesses specializing in Federally-reimbursable items or services (e.g., storefront medical equipment shops). Given the totality of the circumstances, the conduct of the physicians and health clinics under the Proposed Arrangement cannot reasonably be construed as recommending or arranging for the purchase or order of Federally-reimbursable items or services.

Our conclusion that the Proposed Arrangement does not implicate the anti-kickback statute derives from the particular facts presented. In the instant case, we might have reached a different conclusion if, by way of example only, any of the following factors had been present:

- Coupons tied directly or indirectly to the order or purchase of an item or service covered by a Federal health care program (e.g., coupon redemption conditioned directly or indirectly on the purchase of a reimbursable item or service, such as a covered prescription drug or device; or coupons with values that vary based on the purchase of a Federally-reimbursable item or service);
- Distribution of coupons targeted at Federal health care program beneficiaries (e.g., distributed primarily to Federal health care program beneficiaries); or
- Coupons with exceptionally large values.

Any one of these or other factors may have resulted in a different outcome in this opinion.

III. SECTION 1128A(a)(5) OF THE ACT

A further question arises as to whether the Proposed Arrangement violates section 1128A(a)(5) of the Act, which 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, practitioner, or supplier for which payment may be made by Medicare or a State health care program. For purposes of section 1128A(a)(5), "remuneration" includes transfers of items or services for free or for other than fair market value. See section 1128A(a)(6) of the Act.

Under the Proposed Arrangement, the relationship between the coupon distribution and any inducement to a Medicare or Medicaid beneficiary to choose a particular provider for a covered item or service will be attenuated, at best. As noted above, the coupons are not tied (directly or indirectly) to the purchase of any items or services covered by Medicare or Medicaid, nor is the distribution targeted at patients who are likely to purchase or order items or services for which Medicare or Medicaid will reimburse the retailer offering the discount (e.g., the coupons are not distributed only to patients who leave their physician's office with a prescription in hand). The coupons may not be applied to any Medicare- or Medicaid-covered item or service. The Proposed Arrangement is unlikely to give the clinics or physicians that distribute the coupons a significant competitive advantage in the marketplace. For these reasons, in the particular circumstances of the Proposed

Arrangement, the OIG will not subject Company A to sanctions under section 1128A(a)(5) of the Act in connection with the Proposed Arrangement.

IV. CONCLUSION

Based on the information provided, we conclude that, based on the totality of the facts of the Proposed Arrangement (as described and certified in the request letter and supplemental submissions), the Proposed Arrangement does not implicate the anti-kickback statute and that 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 Proposed Arrangement, nor will the OIG impose civil monetary penalties on Company A, in connection with the Proposed Arrangement for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Act.

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 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 requester 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, the fees paid under the Proposed Arrangement are fair market value, 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 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 Proposed 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,

D. McCarty Thornton
Chief Counsel to the Inspector General

1. We are not authorized to opine on "fair market value." See section 1128D(b)(3) of the Act. Therefore, for purposes of this opinion, we have assumed fair market value compensation based on Company A's certifications. If the compensation under the Proposed Arrangement is not at fair market value, this opinion will be without force and effect.

2. Although the Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute, 42 C.F.R. § 1001.952, no safe harbor protects the Proposed Arrangement. The requirements of the personal services and management contracts safe harbor, § 1001.952(d), will not be met here in every case.

3. 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.

4. Company A has certified that the physicians' and clinics' compensation for distributing the coupons will be consistent with fair market value and fixed in arms-length negotiations. See supra note 1. "Per click", "per patient", "per order", and similar payment arrangements are highly disfavored under the anti-kickback statute. Here, compensation under the Proposed Arrangement will not be based directly or indirectly on the volume or value of business -- Federal or otherwise -- that the coupons generate (as might be the case, for example, if the physicians and clinics were paid based on the number of coupons redeemed by, or the value of retail sales made to, their patients). While it is possible that some physicians and clinics may realize an intangible "good will" benefit from distributing retail coupons to patients, the value of any such benefit is likely to be small in these particular circumstances and, given the economic structure of the Proposed Arrangement, accounted for in the arms-length negotiations between Company A and the physicians and clinics.