

*[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:** May 22, 2001

**Posted:** May 29, 2001

[Name and address redacted]

**Re: OIG Advisory Opinion No. 01-6**

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding payments by vendors to a group purchasing organization (“GPO”) owned by entities affiliated with various health care providers that purchase items covered by the GPO’s vendor contracts (the “Arrangement”). In particular, you ask whether the Arrangement would constitute grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the “Act”) or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct, and constitutes a complete description of the facts and agreements among the parties regarding the Arrangement. In issuing this opinion, we have relied solely on the facts and information you presented to us. This opinion is limited to the facts presented. We have not undertaken any independent investigation of such information.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement satisfies the criteria of the group purchasing organizations safe harbor, section 1128B(b)(3)(C) of the Act (and 42 C.F.R. § 1001.952(j)), and thus the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name of requester redacted], under section 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any person other than [name of requester redacted], and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

## I. FACTUAL BACKGROUND

[Name of requester redacted] (“Purchasing Group A”), is a group purchasing organization that negotiates with vendors of health care products (the “Vendors”) for discounted prices on behalf of contracting health care providers (the “Purchasers”) that furnish items and services reimbursable, in whole or in part, by a Federal health care program.

Purchasing Group A itself is a limited partnership consisting of a general partner and four limited partners, each of which is affiliated with a health care system that purchases substantial quantities of items through Purchasing Group A (the “Affiliated Purchasers”). The general partner and one of the limited partners are wholly-owned by [name of health system redacted] (the “Health System”), which also wholly owns one of the Purchasers.<sup>1</sup> Two of the other limited partners are affiliated with health care systems that are former subsidiaries of the Health System. The fourth limited partner in Purchasing Group A is an entity that has no current or former affiliations with the Health System or any of the other Purchasing Group A partners.

In addition to the Affiliated Purchasers, there are several other health care providers that have contracted with Purchasing Group A to purchase health care products and services from Vendors under terms negotiated by Purchasing Group A (the “Non-Affiliated Purchasers”). The Non-Affiliated Purchasers account for approximately [X]% of total purchases and [Y]% of Purchasing Group A revenue.

Each of the Purchasers has entered into a written agreement with Purchasing Group A (the “Participation Agreement”) to permit Purchasing Group A to act as its purchasing agent. For purposes of this advisory opinion, the Arrangement covers the period beginning in calendar year 2000. Under the Participation Agreements, the Purchasers acknowledge that Purchasing Group A will receive group purchasing organization fees quarterly from the Vendors in connection with the Purchasers’ purchases. The Participation Agreements specify: (i) the Vendors who pay a fee to Purchasing Group A of three percent or less of the purchase price of the health care products and services provided by those Vendors, without specifying the exact percentage paid; and (ii) the Vendors who pay a fee to Purchasing Group A of more than three percent, specifying the exact percentage paid by each Vendor.

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<sup>1</sup>The Purchaser that is wholly-owned by the Health System has a “Management Services Agreement” with Purchasing Group A to provide advisory and consulting services, space, and personnel to Purchasing Group A, and negotiates and enters into Purchasing Group A’s vendor agreements on Purchasing Group A’s behalf. The Management Services Agreement is outside the scope of this advisory opinion.

Purchasing Group A discloses in writing to the Purchasers on an annual basis, and to the Secretary of the U.S. Department of Health & Human Services upon request, the amount received from each Vendor with respect to purchases attributable to each Purchaser.

None of the Purchasers is wholly-owned by Purchasing Group A or is a subsidiary of a parent corporation that wholly owns Purchasing Group A (either directly or through another wholly-owned entity).<sup>2</sup>

Purchasing Group A has certified that it will promptly advise the Affiliated Purchasers by letter that the provisions of 42 C.F.R. § 413.17 (Cost to related organizations) may apply to their organizations.

## II. LEGAL ANALYSIS

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 Federal health care programs. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce referrals of items or services paid for 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

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<sup>2</sup>Purchasing Group A has an "Access Agreement" with [name of other GPO redacted] ("Purchasing Group B"), a group purchasing organization for pharmaceutical and biological products. The Access Agreement permits health care providers participating in either Purchasing Group A or Purchasing Group B to enter into Participation Agreements with either Purchasing Group A or Purchasing Group B and have access to either GPO's vendor agreements. None of the entities that have Participation Agreements with Purchasing Group A through the Access Agreement is wholly-owned by Purchasing Group A. Any relationship between Purchasing Group A and Purchasing Group B, including the arrangement described in the Access Agreement, is not within the scope of this advisory opinion.

programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

A number of statutory and regulatory "safe harbors" protect certain arrangements that might otherwise technically violate the anti-kickback statute from prosecution. See section 1128B(b)(3) of the Act; 42 C.F.R. § 1001.952. Safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The relevant safe harbor here is the group purchasing organizations safe harbor. See section 1128B(b)(3)(C) of the Act; 42 C.F.R. § 1001.952(j).

The GPO safe harbor provides protection for payments by a vendor of goods or services to a GPO (the "GPO fee"). The GPO safe harbor contains the following requirements.

- The GPO must be an entity authorized to act as a purchasing agent for a group of individuals or entities who (i) are furnishing services for which payment may be made in whole or in part under Medicare or a State health care program and (ii) are neither wholly-owned by the GPO nor subsidiaries of a parent corporation that wholly owns the GPO (either directly or through another wholly-owned entity).
- The GPO fee must be paid as part of an agreement to furnish goods or services to the group of individuals or entities for which the GPO is the authorized agent.
- The GPO must have a written agreement with each individual or entity that will purchase items or services from the vendor.
- The agreement must accurately reflect the amount of the GPO fee by satisfying one of the following two conditions:
  - First, the agreement may state that the GPO fee will be three percent or less of the purchase price of the goods or services sold by the vendor to the individual or entity.
  - Second, if the GPO fee is greater than three percent, the agreement must state the specific amount of the fee, expressed either as a fixed sum or as a fixed percentage of the value of the purchases made from the vendor by the members of the group under the contract between the vendor and the GPO. If the amount of the GPO fee is not known at the time the agreement is signed, the agreement must state the maximum amount to be paid to the GPO by the vendor.

- Where the entity that receives the goods or services from the vendor is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

See 42 C.F.R. § 1001.952(j).

In the circumstances presented and certified by Purchasing Group A, the fee paid by the Vendors to Purchasing Group A will fit squarely within the GPO safe harbor. Because all of the GPO safe harbor elements are satisfied, the GPO fees paid by the Vendors to Purchasing Group A would not constitute prohibited remuneration under the anti-kickback statute.

This advisory opinion relates only to the GPO fees paid by the Vendors to Purchasing Group A. We express no opinion regarding any other arrangements or remuneration, direct or indirect, between the Vendors and Purchasing Group A or the Purchasers. In addition, given the relationships between Purchasing Group A's limited partners and the Affiliated Purchasers, we express no opinion as to whether, or to what extent, the amounts paid to the GPO must be accounted for on cost reports filed by the Affiliated Purchasers under applicable cost reporting rules and principles, including, but not limited to, 42 C.F.R. § 413.17.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement satisfies the criteria of the group purchasing organizations safe harbor, section 1128B(b)(3)(C) of the Act (and 42 C.F.R. § 1001.952(j)), and thus the OIG would not impose administrative sanctions on [name of requester redacted] under section 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name of requester redacted], 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 or proposed 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, 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 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

