DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

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

Issued: July 16, 2013

Posted: July 23, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 13-09

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal to offer members of a group purchasing organization ("GPO") an equity interest in the GPO's parent organization in exchange for the member: (1) extending its contract with the GPO for five to seven years; (2) committing not to decrease purchasing volume; and (3) relinquishing its right to a portion of the administrative fees that would otherwise have been passed through to the members (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would be 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, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

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 facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the Office of Inspector General ("OIG") could potentially impose administrative sanctions on [name redacted] under sections 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 Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

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

I. FACTUAL BACKGROUND

[Name redacted] (the "Requestor") is a publicly traded company that provides financial and performance improvement technology-based products and services to its clients, most of which are hospitals and health systems. The Requestor's wholly owned subsidiary, [name redacted] (the "Subsidiary"), operates a GPO. The GPO serves various provider types, but its largest members are hospital systems and integrated delivery systems. Revenue earned by the GPO contributes approximately 60% of the Requestor's consolidated net revenue.

The GPO negotiates discounts and other terms in its contracts with vendors, such as manufacturers and distributors, on behalf of the GPO's members. The vendors pay administrative fees to the GPO based on the purchase price of the items and services sold to the GPO's members under the GPO contracts. The administrative fees range from 0.25% to 3% of the purchase prices.

The GPO offers various models of contracts to its members, including a fee-for-service model and a "shareback" model.[1] Under the fee-for-service model, the GPO passes through to the member 100% of the administrative fees that the GPO receives from vendors for that member's purchases. The GPO member pays the GPO a negotiated fee for the GPO's services. There are no minimum purchase requirements for members in a fee-for-service model. Under the shareback model, the GPO passes through to the member a negotiated percentage (generally 50%) of the administrative fees that the GPO collects from vendors for that member's purchases. The member does not pay any fees to the GPO in the shareback model, but does often have minimum purchase requirements.

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[1] We have not been asked to opine on, and express no opinion about, the GPO's existing arrangements.

If the member does not reach its annual minimum purchase requirement, then the shareback amount is reduced pro rata (i.e., if the GPO member purchases 75% of the total amount it contracted to purchase, then the member receives 75% of the shareback amount it would have realized if it had purchased the minimum purchase amount). The Requestor certified that the GPO treats the passed-through administrative fees as discounts under both models, and that the GPO complies with the requirements of an offeror under the discount safe harbor at 42 C.F.R. § 1001.952(h).

Under the Proposed Arrangement, the Requestor would offer certain current and prospective GPO members an equity interest in the Requestor—a publicly traded company—through a private placement or, alternatively, through a secondary public offering that would require stockholder approval. In exchange for the equity interest, the GPO member would extend its current (or a new member would enter into a new) GPO agreement for a term of five to seven years. In addition to agreeing to a new five to seven year contract term, a member accepting the equity interest in the Requestor would be required to commit to not decrease the volume of its purchases through the GPO. This purchase volume would be determined based on an analysis of historical purchases made by the member. Those members electing to accept the equity interest would forego a portion of the administrative fees that otherwise would have been passed through to them. The Requestor would offer three potential options: (1) status quo (no change to the current arrangement); (2) the member would keep 66% of the current shareback and receive an amount of equity roughly equivalent to the market value of the forfeited shareback; or (3) the member would keep 33% of the current shareback and receive an amount of equity roughly equivalent to the market value of the forfeited shareback. To illustrate, assume Member A agreed to forfeit 33% of its shareback, which, based on Member A's past purchasing history, would equate to approximately $1000. If Member A agreed to extend the contract by five years, then Member A would be agreeing to forfeit $5000. Member A would receive a number of shares in the Requestor's company that equate in value to $5000. GPO members currently in fee-for-service arrangements would be permitted to enter into a shareback arrangement under these terms.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable 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, directly or indirectly, overtly or covertly, in cash or in kind.

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. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), 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. 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.

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.

Two safe harbors, both of which were created by statute and interpreted by regulation, potentially apply to the Proposed Arrangement: the GPO safe harbor, 42 C.F.R. § 1001.952(j), and the discount safe harbor, 42 C.F.R. § 1001.952(h). The GPO safe harbor excludes from the definition of "remuneration" certain fees paid by vendors to GPOs. The Proposed Arrangement, however, involves not only fees paid by vendors to the GPO, but also remuneration transferred between the Requestor and the GPO members, which would not be included in the protection of the GPO safe harbor.

The discount safe harbor excludes from the definition of "remuneration" a discount on an item or service for which payment may be made in whole or in part under a Federal health care program for a buyer, seller, or offeror, as long as the relevant entity complies with certain standards. Under the safe harbor, subject to certain exceptions, the term "discount" means "a reduction in the amount a buyer (who buys either directly or through a wholesaler or a group purchasing organization) is charged for an item or service based on an arms-length transaction." A "rebate," for purposes of the safe harbor, is "any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial purchase to which the discount applies, but which is not given at the time of sale." The Centers for Medicare & Medicaid Services ("CMS") requires that distributions of administrative fees paid by GPOs to the GPO members be accounted for as discounts or rebates.[2]

B. Analysis

Section 1128B(b)(2) of the Act prohibits a person from knowingly and willfully offering or paying any remuneration to a person to induce such person to, inter alia, purchase or order any good, facility, service, or item for which payment may be made under a Federal health care program. When a GPO gives anything of value to its members to induce the members to order Federally reimbursable products under the GPO's contracts, the anti-kickback statute is implicated. Under the Proposed Arrangement, the Requestor seeks to transfer an equity interest in the Requestor to GPO members in exchange for the members' agreement to extend their GPO contracts under new terms. The equity interest is a form of remuneration that would not meet any safe harbor to the anti-kickback statute. It is not a discount, because it is not a reduction in price on items or services. Members would be accepting the equity interest in lieu of a portion of the administrative fees that they would have received under their previous contracts. While administrative fees passed through to GPO members could be treated as discounts on the price of goods sold by the vendors, and the GPO and GPO members could meet the reporting and other requirements of the discount safe harbor, the same is not true of an equity interest in the parent company of the GPO.

Arrangements that do not fit in safe harbors must be evaluated on a case-by-case basis based on the totality of facts and circumstances. Under the particular facts presented here, we do not believe that the Proposed Arrangement is sufficiently low risk.

Over the past decade or so, the United States Government Accountability Office ("GAO") and the OIG have conducted several studies on the effect of GPOs on the marketplace. These studies have raised various concerns. For example, one report by the GAO (then, the United States General Accounting Office) noted a concern that the financial flows between hospitals, GPOs, and vendors might result in divergent interests between GPOs and hospitals. In fact, small manufacturers claimed that GPOs have an incentive not to seek the lowest price, because the GPO could earn higher administrative

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[2] See CMS Provider Reimbursement Manual, Part 1, Pub. No. 15-1, ch. 8, § 805: "In addition to facilitating discounts/rebates, GPOs may distribute a portion of their revenue—sometimes referred to as net revenue distributions—to providers or other organizations using the GPO. These distributions are treated like discounts or rebates on the purchases, further reducing a provider's cost of purchases facilitated through the GPO."

fees on higher-priced products.[3] When such a conflict of interest exists, then the GPO may not be serving its purpose of reducing health care costs for its members and, ultimately, for payors. However, even if the GPO did not obtain the lowest cost, members can realize cost savings if the GPO passes a portion of the administrative fees through to its members.

As explained in CMS guidance, when a GPO passes through a portion of its administrative fees to its members, those members are required to treat such distributions as discounts or rebates. See CMS Provider Reimbursement Manual, Part 1, Pub. No. 15-1, ch. 8, § 805. When the distributions are reported as rebates, they could reduce costs to Federal health care programs. Under the Proposed Arrangement, the Requestor would ask members to forego a portion of those distributions in exchange for shares of stock in the publicly traded parent of the GPO. Unlike a discount, the remuneration under the Proposed Arrangement would have no potential to benefit payors, including Federal health care programs.

Three other key elements, in combination, increase the risk of fraud and abuse posed by this particular Proposed Arrangement. First, the Requestor would require members accepting an equity interest to extend their contracts by five to seven years. Second, the equity interest offered would be tied to past purchases. Third, under this extended contract, members would not be permitted to decrease their volume of purchases under the GPO contracts. Thus, members would be locked-in to a contract for five to seven years, regardless of whether the GPO is getting them the best prices. Not only would the remuneration be tied to past purchases, but the members also would be required to maintain at least the same purchasing level going forward. Although the members' returns on investment through their equity interests would not be directly tied to their own future purchases, the GPO's revenues make up a substantial portion of the Requestor's consolidated net revenue. Under the Proposed Arrangement, the GPO would retain more administrative fees, which could boost that revenue and potentially result in higher returns for investors, including the referral source investors.

In sum, we believe that the Proposed Arrangement would allow the Requestor to give remuneration to GPO members to reward past referrals and to induce them to continue purchasing items, including those reimbursable by Federal health care programs, at equal or higher volume as in the past through the GPO, for an extended period of time. For the combination of the reasons stated herein, we cannot conclude that the Proposed Arrangement presents a minimal risk of fraud and abuse.

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[3] Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices, GAO-02-690T, Apr. 30, 2002.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [name redacted] under sections 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 Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor 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 by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein 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, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- 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 which 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 reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General