



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: May 2, 2016

Posted: May 9, 2016

[Names and addresses redacted]

Re: OIG Advisory Opinion No. 16-06

Gentlemen:

We are writing in response to your request for an advisory opinion regarding your proposal for an entity to purchase the remaining five percent ownership interest in a group purchasing organization (“GPO”), which would result in the GPO being wholly owned by an entity whose parent company also wholly owns some of the members of the GPO (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed 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, 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, although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to

induce or reward referrals of Federal health care program business were present, the Office of Inspector General (“OIG”) would not impose administrative sanctions on [names redacted] (collectively, the “Requestors”) 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. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [names redacted], the requestors 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 “GPO Requestor”) is a GPO with over 84,000 members nationwide, including hospitals, nursing facilities, clinics, physician practices, laboratories, and home care or equipment organizations. Prior to July 1, 2015, two entities owned the GPO Requestor in equal shares: [name redacted] (the “Health System”) and [name redacted] (the “Original Co-owner”). The Health System is a nonprofit corporation that owns and operates a healthcare system based in [city and state redacted]. The parent company of the Health System is [name redacted]. The Original Co-owner is a corporation that was owned by a group of approximately 120 health care providers and suppliers located principally in the [region redacted].

The Requestors certified that the Health System believed it could increase efficiencies at the GPO Requestor if it made certain changes to the GPO Requestor’s operations. The Health System claimed that the most effective means to accomplish these efficiencies would be to acquire the interests of the unrelated individual entities that jointly owned half of the GPO Requestor through the Original Co-owner and replace certain management personnel at the GPO Requestor. Through a series of corporate mergers, [name redacted] (the “Subsequent Co-owner”) merged with the Original Co-owner and was the surviving entity. Thus, the Subsequent Co-owner owned 50 percent of the GPO Requestor. Of the 100 shares of common stock the Subsequent Co-owner has issued, the Subsequent Co-owner sold 90 shares to the Health System and 10 shares to another corporation, [name redacted] (“Holdings”). After the mergers and stock sales, the Health System now owns a total of 95 percent of the GPO Requestor, and Holdings owns the remaining five percent. We have not been asked about, and we express no opinion regarding, the transactions related to the mergers and stock sales.

Under the Proposed Arrangement, the Health System would purchase the remaining 10 shares of the Subsequent Co-owner common stock from Holdings, which would result in the Health System being the sole owner of the GPO Requestor. The Requestors have certified that the GPO Requestor would continue to serve the same market with similar

and improved results. It would continue to operate in much the same way as in the past, including negotiating with vendors regarding products and pricing to be offered to the GPO Requestor's members, and receiving administrative fees from vendors based on a small percentage of the value of sales to members. The Requestors certified that the GPO Requestor has written agreements with each member and that those agreements specify the vendor fees in writing. Further, the GPO Requestor discloses, and would continue to disclose, in writing to each member provider or supplier, at least annually, and to the Secretary of Health and Human Services (the "Secretary") upon request, the amount received from each vendor with respect to purchases made by or on behalf of the provider or supplier. Further, the GPO Requestor maintains, and would continue to maintain, records for each member regarding reductions in price obtained by the GPO Requestor, as well as any portion of vendor administrative fees that are distributed to members ("shareback"). The Requestors certified that the GPO Requestor provides, and would continue to provide, its members with all necessary records and information to enable them to make all appropriate disclosures of discounts required to comply with the discount exception to the anti-kickback statute, and the discount safe harbor. The Requestors certified that members of the GPO Requestor that are owned or operated by the Health System (approximately 800 of the 84,000 members) are, and would continue to be, subject to GPO contract terms and conditions negotiated on the same basis as members unaffiliated with the Health System (i.e., eligible to use the same vendor discount terms and to negotiate sharebacks based on volume and commitment).

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 Proposed Arrangement would involve: (1) the discounts that the GPO Requestor negotiates from vendors on behalf of its members; (2) the GPO Requestor's distribution to members of administrative fees; and (3) the administrative fees that the GPO Requestor collects from vendors. The discount safe harbor, 42 C.F.R. § 1001.952(h), could apply to the remuneration included in items (1) and (2), and the GPO safe harbor, 42 C.F.R. § 1001.952(j), could apply to the remuneration included in item (3).

The discount safe harbor excludes from the definition of "remuneration," for purposes of the anti-kickback statute, a discount on an item or service for which payment may be made in whole or in part under Medicare, Medicaid, or other Federal health care programs for a buyer, seller, or offeror of a discount who is not a seller, as long as the relevant entity complies with certain standards. Under the safe harbor, the term "discount" includes a "rebate," which is defined, for purposes of the discount safe harbor, as "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." 42 C.F.R. § 1001.952(h)(4). This safe harbor, if applicable, would protect a discount offered by a seller to a GPO, by a seller through a GPO to a buyer, and by a GPO to a buyer. Generally, to comply with the safe harbor, a GPO would have to inform the buyer of the buyer's obligation to report the discount, and the GPO must refrain from doing anything that would impede the buyer's ability to meet its reporting requirements. Id. § 1001.952(h)(3).

As noted above, the safe harbor for GPOs is also potentially applicable to the Proposed Arrangement. It excludes from the definition of "remuneration" certain fees paid by vendors to GPOs. To qualify for protection under the GPO safe harbor, a GPO must have a written agreement with each individual or entity for which items or services are furnished. That agreement must either provide that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of three

percent or less of the purchase price of the goods or services provided by that vendor or, in the event the fee paid to the GPO is not fixed at three percent or less of the purchase price of the goods or services, specify the amount (or if not known, the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the vendor by the members of the group under the contract between the vendor and the GPO). 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. As explained in the preamble to the final regulations, the exception is not intended to protect fees to arrange for referrals or recommendations within a single entity. See Preamble to Final Rule: OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35982 (July 29, 1991) (the “1991 Final Rule”). Therefore, the safe harbor provides that “GPO” means an entity authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services for which payment may be made in whole or in part under Medicare, Medicaid or other Federal health care programs, and who 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).

B. Analysis

The Requestors certified that the GPO Requestor satisfies, and would continue to satisfy, all of the elements of the discount safe harbor set forth at 42 C.F.R. § 1001.952(h). Specifically, the GPO Requestor would continue to provide its members with all necessary records to enable them to make all appropriate disclosures of discounts negotiated by the GPO Requestor and received by the members, and would refrain from doing anything that would impede the member from meeting its obligations under this discount safe harbor.

However, even if the discounts offered and given to members, and the administrative fees passed through the GPO Requestor to members as rebates, would qualify for protection under the discount safe harbor, the discount safe harbor would not protect the administrative fees obtained by the GPO Requestor from its vendors. Those fees must be analyzed under the GPO safe harbor. According to the Requestors’ certifications, the GPO Requestor and its arrangements currently meet the terms of the GPO safe harbor. Specifically, the Requestors certified that the GPO Requestor has agreements with each vendor that specify the vendor fees in writing, and the GPO Requestor discloses in writing to each provider and supplier of health care services 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 provider or supplier. The GPO Requestor currently is not wholly owned by the same entity that owns any of its members. The Requestors certified that, under the Proposed Arrangement, all requirements of the GPO safe harbor would continue to be met, except that the GPO Requestor would be wholly owned by the same entity that also wholly owns approximately one percent of the pool of the GPO

Requestor’s members. In other words, the Proposed Arrangement would cause the GPO Requestor to fall outside the definition of a “GPO” that would be protected by the GPO safe harbor. However, absence of safe harbor protection is not fatal. Instead, such arrangements must be considered on a case-by-case basis, to determine their potential for risk to Federal health care programs.

The key question here, then, is whether the Health System’s acquisition of the remaining shares of the Subsequent Co-owner’s common stock, resulting in the GPO Requestor being wholly owned by the same entity that owns nearly one percent of the pool of GPO Requestor’s members, increases the risk to Federal health care programs. As we explain further below, we do not believe that the Proposed Arrangement increases that risk.

To analyze this issue, we begin with the history of the GPO safe harbor. In 1986, Congress amended the anti-kickback statute to create an exception for amounts paid by vendors to GPOs, as long as certain conditions were met. According to the legislative history, Congress believed that GPOs could “help reduce health care costs for the government and the private sector alike by enabling a group of purchasers to obtain substantial volume discounts on the prices they are charged.”¹ Subsequently, the OIG promulgated the regulatory safe harbor described above. The safe harbor as initially proposed in 1989 closely followed the language of the statutory exception.² During the notice and comment period, a commenter asked the OIG to clarify the term “GPO.” As described in the 1991 Final Rule, that commenter asked whether a nursing home chain requesting percentage payments from laboratories as GPO fees would qualify for the safe harbor. As we stated in that preamble, we did not believe that “such a solicitation sanitizes the illegality when it is made indirectly by a wholly-owned subsidiary of the nursing home, instead of directly by the nursing home itself.”³ In the 1991 Final Rule, we included a definition that would prevent entities from establishing wholly owned subsidiaries as GPOs to be able to extract fees from vendors in exchange for referrals. Such an “entity” would not be the type of purchasing agent that Congress envisioned when creating the exception.

Under the Proposed Arrangement, although the GPO Requestor would be wholly owned by the same entity that also owns some of the GPO Requestor’s members, the GPO Requestor’s scenario is otherwise entirely different from the scenario described in the 1991 Final Rule. The members that are wholly owned by the same entity that also would wholly own the GPO Requestor constitute only approximately one percent of the GPO Requestor’s total membership. The Requestors certified that all members are, and would continue to be, subject to GPO contract terms and conditions negotiated on the same

¹ H.R. Rep. No. 99-727, at 73 (1986), reprinted in 1986 U.S.C.C.A.N. 3607, 3663.

² Proposed Rule: Anti-kickback Provisions, 54 Fed. Reg. 3088 (Jan. 23, 1989).

³ 56 Fed. Reg. 35952, 35982 (July 29, 1991).

basis as members unaffiliated with the Health System (e.g., the members of the GPO Requestor that are under common ownership would not receive more (or less) favorable discounts or shareback calculations than unaffiliated members). The Requestors' certifications indicate that, despite the GPO Requestor's proposed ownership change, the GPO Requestor would continue to operate as a purchasing agent for a group of individuals and entities, the vast majority of which are unrelated to the GPO Requestor. We therefore do not view the Health System's acquisition of the remaining five percent of the GPO Requestor as increasing the risk to Federal health care programs.

In sum, although the Proposed Arrangement cannot receive GPO safe harbor protection because of the proposed ownership structure of the GPO Requestor, based on the totality of the facts and circumstances described herein, and for the reasons stated above, we conclude that the Proposed Arrangement presents an acceptably low risk of fraud and abuse in connection with the anti-kickback statute.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [names 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. This opinion is limited to the Proposed Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors 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 [names redacted] to provide 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 will not proceed against [names redacted] 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, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action that is part of the Proposed Arrangement 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General