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 30, 2018

Posted: August 6, 2018

[Name and address redacted]

Re: OIG Advisory Opinion No. 18-07

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding a proposal from a group purchasing organization ("GPO") to serve as a purchasing agent on behalf of certain GPO-affiliated health care facilities on the same terms and conditions that apply to its unaffiliated members (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 [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. 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 [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] ("Requestor") is a GPO that has provided hospital group purchasing services to its members for over 20 years. Originally, Requestor operated as a division of [name redacted] (the "Management Company"). Requestor became a fully operational corporate entity in 2010 and now is a wholly owned subsidiary of the Management Company. Until April 29, 2016, the Management Company was a wholly owned subsidiary of [name redacted] (the "Hospital Owner"), which owns and operates general acute care hospitals. The Hospital Owner formed [name redacted] (the "Parent Organization") by spinning off the Management Company and a number of the Hospital Owner's hospitals. The Parent Organization, which is an independent public company, currently owns 31 hospitals ("Affiliated Facilities") through various subsidiaries and affiliates that previously were owned by the Hospital Owner and indirectly owns Requestor. The Affiliated Facilities are separate legal entities located in 15 different states and provide a broad range of general hospital inpatient and outpatient health care services. We have not been asked to opine, and we express no opinion, on these corporate transactions or any activities that transpired before the transactions.

Requestor provided GPO services to over 100 member hospitals and health care facilities before the corporate spin off and currently provides such services to 134 member hospitals and other health care facilities that are not Affiliated Facilities (collectively, "Current Members"). As a GPO, Requestor contracts with vendors and negotiates discounts on behalf of its Current Members. Requestor certified that it negotiates discounts for its Current Members on products and services that extend beyond a typical hospital supply portfolio, including, but not limited to, information technology platforms, emergency department services and staffing, physician recruitment, telemedicine physician consults, human resources personnel and services, and refurbished equipment ("Specialized Products

and Services"). Requestor provides its Current Members access to standard hospital equipment and supplies through an arrangement with another, unrelated GPO.[1]

Requestor certified that it does not and would not enter into contracts with its specialized service vendors, including physicians or physician organizations, to provide Specialized Products and Services. Instead, the contracts between Requestor and each vendor set forth a catalog of the products and services offered by the vendor to Requestor's Current Members and the specific discounts available to Current Members through the vendor. Each Current Member then can enter into a separate agreement with each vendor that sets forth the actual products and services to be provided to the Current Member, the term and scope of such products and services, the discounted rate available to the Current Member, and any other terms governing the relationship between the contracting parties. Requestor certified that the aggregate purchasing power of the Current Members permits Requestor to negotiate significant discounts from vendors, and its contracts for Specialized Products and Services generally result in 18 percent cost savings for its Current Members compared to competitor GPOs' prices.

Requestor certified that its existing arrangements meet the requirements of the GPO safe harbor. Specifically, Requestor has written agreements with each Current Member providing that participating vendors pay an administrative fee of three percent or less of the purchase price of the goods or services provided by the vendor for purchases made on behalf of the Current Member (or, if the agreed-upon administrative fees exceed three percent, the contract specifies the amount or maximum amount of the administrative fee for each participating vendor for purchases made on behalf of the member). Requestor provides to each Current Member, and to the Secretary of Health and Human Services upon request, an annual statement disclosing the amount received from each vendor for purchases made on behalf of the Current Member. With the exception of three independently negotiated arrangements,[2] Requestor certified that it does not share administrative fees with its Current Members.

Under the Proposed Arrangement, Requestor seeks to expand its membership to include Affiliated Facilities. Requestor certified that the unrelated GPO through which Affiliated Facilities and Current Members purchase many of their hospital supplies, services, and equipment does not make available many of the Specialized Products and Services that Requestor offers. Therefore, if an Affiliated Facility desires to purchase such Specialized Products and Services, the Affiliated Facility must negotiate pricing directly with the

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

[2] We have not been asked to opine, and offer no opinion, on these three arrangements.

applicable vendor. Permitting the Affiliated Facilities to be members of Requestor would allow them to access the discounts on Specialized Products and Services that are available to Current Members.[3]

Requestor certified that if it expanded its membership to include Affiliated Facilities, Affiliated Facilities would constitute approximately 35 percent of its members and approximately 20 percent of its anticipated purchasing volume. Requestor certified that it would continue to operate as a GPO for each Current Member and Affiliated Facility (collectively, "Proposed Members") on a uniform basis. Requestor would aggregate the purchasing volume of all Proposed Members and use the increased purchasing power to negotiate greater discounts, which would be reflected, where applicable, in related costs that are reimbursed by Federal health care programs. Requestor also certified it would disclose to all Proposed Members, at least annually, and to the Secretary upon request, any administrative fees received from each vendor. Other than the three arrangements referenced above, Requestor would not distribute administrative fees to any Proposed Member.

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.

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[3] As with Current Members, any contracts for physician services or with physician service organizations would be between the Affiliated Member and the vendor. Although Requestor asserts that these contracts are, and would continue to be, designed to comply with the anti-kickback statute, section 1877 of the Act (also known as the Stark law), and other laws, Requestor does not draft or review these contracts. We express no opinion on the contracts between Current Members and vendors or proposed contracts between Affiliated Members and vendors. We have not been asked to opine, and we express no opinion, regarding whether the Stark law would apply to financial relationships between the Affiliated Facilities and any physicians providing Specialized Products and Services under the Proposed Arrangement.

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. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); 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 $100,000, imprisonment up to ten 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 U.S. 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.

The safe harbor for GPOs, which Congress enacted by statute[4] and the OIG interpreted at 42 C.F.R. § 1001.952(j), potentially applies to the Proposed Arrangement. It excludes from the definition of "remuneration" certain fees paid by vendors to GPOs, which otherwise could constitute remuneration to induce, reward, or arrange for referrals of Federal health care program business. 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 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

[4] Section 1128B(b)(3)(C) of the Act.

within a single entity. See Preamble to Final Rule: OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,982 (July 29, 1991) ("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

Under the Proposed Arrangement, Requestor would fail to meet the safe harbor's definition of a "GPO" because the Affiliated Facilities Requestor seeks to include as Proposed Members share the same parent organization as Requestor. Arrangements that implicate the anti-kickback statute but do not fit in a safe harbor must be evaluated on a case-by-case basis, based on the totality of the facts and circumstances, to determine their potential for risk to Federal health care programs.

In addressing this issue, we turn to 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 related to this exception, 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."[5] Subsequently, the OIG promulgated the regulatory safe harbor described above. In the years following the promulgation of the regulatory safe harbor, both Congress and the OIG began to question whether GPOs were achieving the key goal articulated by Congress of reducing health care costs for the government and the private sector.[6] Nevertheless, the safe harbor continues to protect GPO arrangements that meet the stated conditions.

We also have explained that, when a GPO is wholly owned by the same parent organization as many of the participants, there is an increased risk that administrative fees collected by the GPO could be illegal inducements for referrals or recommendations. For example, in the preamble of the 1991 Final Rule, we addressed a comment asking whether a nursing

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

[6] See, e.g., Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices, GAO-02-690T, Apr. 30, 2002, available at https://www.gao.gov/products/GAO-02-690T and Review of Revenue from Vendors at Three Group Purchasing Organizations and Their Members, A-05-03-00074, Jan. 19, 2005, available at https://oig.hhs.gov/oas/reports/region5/50300074.pdf.

home chain that requested percentage payments from laboratories as "GPO fees" in return for the referral of laboratory services could meet the definition of a "GPO." We explained:

> a chain of nursing homes that are wholly owned subsidiaries of a single corporate entity for all practical purposes constitutes a single entity and not a "group" of entities. . . . [W]e do not believe it appropriate for a nursing home chain to qualify as a GPO and request "GPO fees" for referrals. If a nursing home directly requested such a fee it would appear to represent an illegal inducement. We see no reason how 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.

Although Requestor is wholly owned by the same entity that also owns some of the Proposed Members, Requestor's scenario is otherwise entirely distinguishable from the scenario described in the 1991 Final Rule. We therefore believe, for the following reasons, that Requestor's addition of the Affiliated Facilities under the Proposed Arrangement would not materially increase the risk of fraud and abuse under the anti-kickback statute.

First, Requestor already exists as a GPO that, according to Requestor's certifications, complies with the GPO safe harbor. Requestor currently serves over 100 unaffiliated facilities. Although adding facilities under common ownership would cause Requestor to fall outside of the definition of a "GPO" set forth in the safe harbor, we do not believe that adding such facilities would increase the risk to Federal health care programs. In fact, adding more facilities could increase Requestor's ability to obtain lower prices on goods and services due to the potential for increased volume purchasing.

Second, the Affiliated Facilities would constitute approximately 35 percent of the Proposed Members and approximately 20 percent of sales volume. Requestor certified that all Proposed Members would be subject to the same GPO contract terms and conditions. In other words, Requestor would continue to operate as a purchasing agent for a group of individuals and entities, the majority of which are unrelated to Requestor. We therefore do not believe that adding the Affiliated Facilities to Requestor's membership would increase the risk to Federal health care programs.

Third, the Parent Organization is an independent, public company that owns, directly or indirectly, a number of hospitals and other health care-related organizations, each of which is a separate legal entity. Requestor has been providing GPO services for over twenty years and continues to provide those services to Current Members. Thus, the Proposed Arrangement, under which Requestor would add Affiliated Facilities that are owned by the same public company that owns Requestor, is readily distinguishable from scenarios in which wholly owned subsidiaries of a single corporate entity are essentially a single entity seeking referral fees.

In sum, although the Proposed Arrangement cannot receive GPO safe harbor protection because of the ownership structure of Requestor's Parent Organization, based on the totality of the facts and circumstances described herein, and for the reasons stated above, we conclude that the Proposed Arrangement would present an acceptably low risk of fraud and abuse under 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 [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. 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 [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 will not proceed against [name 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 [name 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,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs