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OIG APPROVES OF GPO SERVING WHOLLY OWNED ENTITIES

On August 6, 2018, the Department of Health and Human Services Office of Inspector General ("OIG") published Advisory Opinion 18-07, approving an arrangement whereby a group purchasing organization ("GPO") would serve as a purchasing agent on behalf of health care facilities under a common parent organization with the GPO (the "Proposed Arrangement"). This is the third of this type of arrangement approved by OIG, which concluded that although the Proposed Arrangement does not meet the GPO safe harbor to the Anti-Kickback Statute ("AKS"), OIG would not impose sanctions because the Proposed Arrangement presented an acceptably low risk of fraud abuse based on the totality of the facts and circumstances.

BACKGROUND

Requesting Party

The requesting party ("Requestor") is a GPO that provides hospital group purchasing services to 134 unaffiliated hospitals and health care facilities ("Current Members"). The Requestor is indirectly owned by a parent organization that also owns 31 hospitals ("Affiliated Facilities"). As part of the GPO services, the Requestor negotiates discounts on products and services for the Current Members that extend beyond the usual hospital supply selection, including IT platforms, emergency department services and staffing, physician recruitment, telemedicine physician consults, HR personnel and services and refurbished equipment ("Specialized Products and Services"). The Requestor certified that it does not and would not enter into contracts with specialized service vendors, including physicians or physician organizations, to provide Specialized Products and Services. Rather, the contracts between the Requestor and the applicable vendors provide a catalog of the products and services, and applicable discounts, offered by the vendor to the Current Members. Each Current Member may then enter into separate agreements with each vendor that set forth the actual terms of the relationship, including the products and/or services, discounts and scope of the arrangements. The Requestor also provides its Current Members with access to standard hospital equipment and supplies through an arrangement with another, unrelated GPO ("Unrelated GPO").

Proposed Arrangement

Under the Proposed Arrangement, the Requestor desired to expand its membership to include the Affiliated Facilities. The Unrelated GPO does not provide several of the Specialized Products and Services that are available through the Requestor. Accordingly, each Affiliated Facility must negotiate terms and pricing directly with the vendor for Specialized Products and Services. If the Affiliated Facilities were permitted to be members of the Requestor, then they would be able to access the discounts on Specialized Products and Services that are available to Current Members. The Requestor certified to OIG that it would continue to operate as a GPO on a uniform basis for both Current Members and Affiliated Facilities (collectively, "Proposed Members"). The Requestor could aggregate purchasing volume of all Proposed Members to increase purchasing power and negotiate greater discounts that would be reflected in related costs that are reimbursed by federal health care programs where applicable.

OIG ANALYSIS

The AKS makes it a criminal offense to knowingly and willfully offer or receive remuneration to induce or reward referrals of items or services reimbursable by federal health care programs. If just one purpose of an arrangement is to induce or reward referrals, the arrangement violates the AKS. The U.S. Department of Health and Human Services ("HHS") has promulgated safe harbor regulations that define practices that are not subject to the AKS because such practices would be unlikely to result in fraud or abuse. However, safe harbor protection is only afforded to arrangements that squarely meet all of the conditions set forth in the applicable safe harbor.

The GPO safe harbor to the AKS allows a vendor to pay fees to a GPO if all of the following requirements are met:

- The GPO must have a written agreement with each individual or entity for which items or services are furnished;
- The 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, specify the amount the GPO will be paid by each vendor; and

- 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 at least annually, and to the Secretary of HHS upon request, the amount received from each vendor with respect to purchases made by or on behalf of the entity.

In order to take advantage of the GPO safe harbor, an entity must meet the definition of a "GPO." The GPO safe harbor is not intended to protect fees to arrange for referrals within a single entity. Consequently, the safe harbor's definition of GPO refers to an entity authorized to act as a purchasing agent for members who are furnishing services for which payment may be made under state or federal health care programs *and who are not wholly owned by the GPO or subsidiaries of a parent corporation that wholly owns the GPO*. OIG found that the Requestor failed to meet the definition of GPO in the safe harbor because the Affiliated Facilities share the same parent organization as the Requestor.

Because the Proposed Arrangement implicated the AKS and did not meet the GPO safe harbor, OIG analyzed the Proposed Arrangement under the totality of the facts and circumstances standard to determine its potential risk to federal health care programs. Nevertheless, OIG opined that the Requestor's addition of the Affiliated Facilities under the Proposed Arrangement would not materially increase the risk of fraud and abuse under the AKS for the following reasons:

1. The Requestor already operates as a GPO that complies with the GPO safe harbor according to the Requestor's certifications. OIG noted that while adding facilities under common ownership would cause the Requestor to fall outside of the definition of "GPO" in the safe harbor, OIG did not believe that adding the Affiliated Facilities would increase the risk of fraud and abuse. Conversely, adding the Affiliated Facilities could actually increase the Requestor's ability to obtain lower prices on goods and services because of the potential for increased volume purchasing.
2. The Affiliated Facilities would comprise 35 percent of the Proposed Members and roughly 20 percent of sales volume. The Requestor declared that all Proposed Members would be subject to identical GPO contract terms and conditions. Simply stated, the Requestor would continue to function as the purchasing agent for the group of individuals and entities, of which the vast majority are unrelated to the Requestor.
3. The parent organization is an independent company that owns (directly or indirectly) multiple hospitals and other health care related organizations which are all separate legal entities. The Requestor has provided GPO services to Current Members for over twenty years and continues to do so today. As such, the Proposed Arrangement, where the Requestor would add Affiliated Facilities owned by the same public company that owns the Requestor, can be easily distinguished from arrangements where wholly owned subsidiaries under a single corporate entity are essentially a single entity seeking referral fees.

Although the Proposed Arrangement does not fall under the GPO safe harbor because of the ownership structure of the Requestor's parent organization, OIG concluded based on the totality of the facts and circumstances that the Proposed Arrangement would present an acceptably low risk of fraud and abuse under the AKS.

PRACTICAL TAKEAWAYS

This is the third time in the last six years that OIG has approved an arrangement in which the GPO would contain affiliated entities, suggesting an emerging trend toward permitting the operation of wholly owned GPOs so long as certain safeguards exist.

- In Advisory Opinion 12-01*, OIG approved the creation of a wholly owned GPO that would contain primarily affiliated members but would be open to adding unaffiliated members in the future. OIG noted several safeguards that it believed sufficiently mitigated the risk of running afoul of the AKS.
- Then, in Advisory Opinion 16-06, OIG approved an arrangement in which a health system that owned 95 percent of a GPO, as well as one percent of the GPO members, was permitted to acquire the remaining five percent of the ownership shares, such that the GPO would then be wholly owned by the same entity that owned a small percentage of the GPO's members. OIG also highlighted that regardless of whether a GPO member was affiliated, the terms and conditions available under the vendor agreements were the same.
- Now, under the Proposed Arrangement, OIG approved the composition of a GPO's membership in which the percentage of affiliated entities was 35 percent and the affiliated entities' sales volume was 20 percent. Additionally, OIG reinforced the importance of all GPO members having access to the same terms and conditions. While OIG has approved varying percentages of affiliated entity membership

in a GPO, the common theme is that certain safeguards must be in place to establish an acceptably low risk of fraud and abuse under the AKS. The level of safeguards appears to correspond with the percentages of affiliated members, where a GPO with a higher percentage of affiliated membership needs to establish more safeguards. The key safeguard in both Advisory Opinion 16-06 and the current scenario is that all members are subject to the same GPO contract terms and conditions. This concept could be paramount in the eyes of OIG for other entities exploring the idea of creating a wholly owned GPO.

The Proposed Arrangement also provided OIG with the opportunity to acknowledge the procurement of Specialty Products and Services, which included arrangements for physician services or with physician service organizations through a GPO. While OIG did not offer an opinion regarding whether the Stark Law would be implicated with respect to the financial relationships between Proposed Members, including Affiliated Facilities, and any physicians providing Specialized Products and Services under the Proposed Arrangements, it remains imperative that the individual financial relationships between referring entities be reviewed for compliance with Stark.

As the health care industry continues to focus its efforts toward value-based purchasing and as providers continue to assess supply chain purchasing strategies, these Advisory Opinions suggest that creating a wholly owned GPO may not be problematic so long as certain safeguards exist.

If you have any questions or would like additional information about this topic, please contact:

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*Advisory Opinion 12-01 was obtained by Hall Render.