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OIG Okays Purchasing Structure Outside of Strict Compliance with Discount and GPO Safe Harbors

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The OIG, in Advisory Opinion 12-01, approved a proposed purchasing structure involving a GPO that would be wholly owned by an entity that also wholly owns many of the potential GPO participants, and under which a portion of the vendor payments received by the GPO would be passed through to GPO participants. <u>Bill Mathias</u> and <u>Aaron Rabinowitz</u> offer further details and discuss the OIG's analysis the proposed arrangement.

On March 8, 2012, the OIG issued a favorable advisory opinion (OIG Advisory Opinion 12-01 [PDF]) relating to a proposed purchasing structure outside of the narrow confines of the discount and group purchasing organization (GPO) safe harbors. Under the proposed arrangement, a GPO would be wholly owned by an entity that also wholly owns many of the potential participants in the GPO, and a portion of the payments received by the GPO from vendors would be passed through to participants in the GPO. While finding that the proposed GPO arrangement potentially implicated the antikickback statute, the OIG refused to impose administrative sanctions against the health system or its subsidiaries (the Requestor).

The Requestor consists of several parties, including the parent organization of a national health system comprised primarily of nonprofit corporations that own and operate local health care facilities. Each nonprofit corporation is a separate legal entity, and an indirect subsidiary of the parent organization. The Requestor also includes a first tier subsidiary of the parent organization that is responsible for oversight and governance of the nonprofit corporations. Finally, the Requestor also includes an LLC that is a wholly owned subsidiary of the first-tier subsidiary, and is responsible for all supply chain, resource, and materials management operations.

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Under the proposed arrangement, the LLC seeks to form and operate a GPO for the benefit of the nonprofit corporations and other related and affiliated organizations in the health care industry. Although the initial participants in the proposed GPO would likely be the nonprofit corporations and other organizations affiliated with the parent organization or its subsidiaries, it would be open to participation by unrelated health systems and other non-affiliated participants. The proposed arrangement would involve: (1) discounts that the proposed GPO would negotiate from vendors on behalf of its participants; (2) the proposed GPO's distribution to participants of administrative fees that exceed its costs, which the proposed GPO would require the participants to treat as discounts; and (3) the administrative fees that the proposed GPO would collect from vendors and retain.

The OIG noted that the discount safe harbor could apply to the initial discounts and administrative fees passed through the proposed GPO to participants as rebates. The discount safe harbor excludes from the definition of remuneration, for purposes of the antikickback 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, provided the relevant entity complies with certain standards. Under the safe harbor, the term discount includes a rebate, which is defined 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." Here, the Requestor certified that the proposed GPO would satisfy all of the elements of the discount safe harbor set forth at 42 C.F.R. § 1001.952(h).

However, the OIG concluded that the discount safe harbor would not protect the portion of the administrative fee retained by the proposed GPO. Moreover, these administrative fees would not be protected by the GPO safe harbor because the proposed GPO and most of the affiliated participants would be wholly owned by the parent organization or its first-tier subsidiary. As the OIG explained, the GPO safe harbor was not intended to protect fees to arrange for referrals or recommendations within a single entity. The GPO safe harbor provides that GPO does not include an

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entity that is authorized to act as a purchasing agent for a group of entities if they are wholly owned by the GPO or subsidiaries of a parent corporation that wholly owns the GPO.

The absence of safe harbor protection did not prove fatal. The OIG identified several safeguards in the proposed arrangement. It refused to subject the Requestor to administrative sanctions under the antikickback statute, concluding that there was an "acceptably low level of risk." The safeguards identified by the OIG were as follows:

First, the proposed arrangement includes safeguards to mitigate the risk that the administrative fees collected by the wholly owned GPO could be illegal inducements to induce referrals or recommendations. For example, the proposed GPO would retain only the administrative fees necessary to offset its costs. Any administrative fees above its costs would be paid to the participants based on their purchasing and would be required to be reported as rebates. Thus, there would be no incentive for the proposed GPO to negotiate higher administrative fees in lieu of discounts.

Second, the Requestor certified that the GPO participation agreements would require all affiliated participants to report the full amount of their administrative fees as rebates, and net such amounts against the cost of purchases. In addition, the parent organization, the first-tier subsidiary, the proposed GPO, and the affiliated participants would comply with the Medicare cost reporting rules applicable to central-purchasing activities. The non-affiliated participants would be required to report the full amount of any distributed administrative fees as rebates and net the amounts against the costs of purchases.

Third, the proposed GPO would include disclosures on its website to inform vendors and the public that the administrative fees in excess of its costs may be passed through to participants. The proposed GPO would also directly inform vendors that they may have reporting requirements related to any administrative fees that do not qualify as bona fide service fees.





Fourth, the Requestor certified that the proposed GPO would not be restricted to affiliated participants, which would provide an incentive to increase its number of participants and remain competitive in the marketplace, seeking out the best prices and services.

Finally, the Requestor certified that it would continue to use multiple resources to seek out the best value for the participants, even if such purchases would not be through the proposed GPO. For example, the parent organization would continue to direct its purchasing volume through independent GPOs when they can obtain a lower cost from suppliers than the proposed GPO.

Ober|Kaler's Comments

Advisory Opinion 12-01 is consistent with past statements by the OIG that have narrowly interpreted the protections of the discount and GPO safe harbors. Nevertheless, the OIG's approval of the proposed purchasing arrangement seems consistent with the advice that many in the health care industry have been getting for years. By treating GPO administrative fees that are distributed to the purchasing GPO members as discounts and offsetting them against purchases, the benefit of the GPO fees are essentially passed along to Medicare. The netting of distributions and purchases, thus, appears to effectively eliminate the risk of fraud and abuse. Those interested in pursuing a similar purchasing strategy should consult with experienced fraud and abuse counsel and seek to incorporate the safeguards identified in the advisory opinion.