OIG APPROVES WHOLLY OWNED GROUP PURCHASING ORGANIZATION IN ADVISORY OPINION 16-06

On May 9, 2016, the Department of Health and Human Services Office of Inspector General ("OIG") posted Advisory Opinion 16-06, addressing a proposed arrangement whereby a health system ("Health System") would wholly own the requesting group purchasing organization ("GPO"), as well as approximately one percent of the GPO's members ("Proposed Arrangement"). OIG concluded that the Proposed Arrangement could potentially constitute prohibited remuneration under the Anti-Kickback Statute ("AKS") but that OIG would not impose sanctions against the GPO or Health System due to the low risk of the Proposed Arrangement.

PROPOSED ARRANGEMENT

The GPO proposed that its Health System owner, which already owned 95 percent of the GPO, purchase the remaining shares so that the GPO would be wholly owned by the Health System. The Health System also already owned approximately 800 of the 84,000 GPO members. The GPO certified that it has written agreements with each member and that those agreements specify the vendor fees in writing. Additionally, the GPO certified that it would operate similarly as it had in the past to negotiate pricing for its members and receive administrative fees from its vendors and that members (regardless of affiliation status) would be subject to the same contract terms and conditions. Further, the GPO would continue to disclose in writing to each member the amounts received from each vendor and would continue to maintain records for each member regarding the GPO's reductions in price and "sharebacks" (portions of vendor administrative fees that are distributed to members). The GPO also certified that it would provide all members with necessary records and information to make appropriate disclosures pursuant to the AKS discount exception and safe harbor.

ANALYSIS

First, OIG established that the discount safe harbor and GPO safe harbor could potentially apply to the Proposed Arrangement. OIG explained that the discount safe harbor would apply to: 1) the discounts that the GPO negotiates from vendors on behalf of its members; and 2) the GPO's distribution of administrative fees to its members. The GPO safe harbor could apply to the administrative fees that the GPO collects from vendors.

The GPO certified that all elements of the discount safe harbor would be satisfied under the Proposed Arrangement. While the discounts and administrative fees passed through to members would qualify for protection under the discount safe harbor, OIG was concerned that the administrative fees the GPO collects from vendors were still at issue. Under the Proposed Arrangement, the GPO would no longer meet the definition of "group purchasing organization" under the GPO safe harbor since the GPO would be wholly owned by the same entity that also wholly owns some of the GPO members. Thus, those administrative fees would not be protected under the GPO safe harbor.

Nonetheless, OIG found that the Proposed Arrangement did not increase the risk to federal health care programs, even though it would not meet the GPO safe harbor. OIG analyzed the legislative history of the GPO safe harbor and specifically the 1991 Final Rule that included a definition that prevented entities from establishing wholly owned subsidiaries as GPOs in order to get fees from vendors in exchange for referrals. OIG concluded that the Proposed Arrangement here was sufficiently distinct from the scenario contemplated in the 1991 Final Rule. Here, the members wholly owned by the Health System constitute approximately one percent of the GPO's total membership, and the members would all be subject to the same terms and conditions negotiated on the same basis. In other words, there would be no favorable treatment for GPO members that are wholly owned by the Health System.

PRACTICAL TAKEAWAYS

Recently, the government has expressed more concern with GPO arrangements. Specifically, Congress and OIG have questioned whether GPOs were actually achieving the goals of the GPO safe harbor, including reducing health care costs for both the private sector and government. Further, the Government Accountability Office ("GAO") published a GPO report in 2014 expressing concern about GPO administrative fees. The GAO recommended in its report that OIG monitor whether hospitals are appropriately reporting administrative fee revenues on their Medicare cost reports.

This Advisory Opinion, along with Advisory Opinion 12-01, may allow health systems to assess and reevaluate their GPO relationships. Health

systems may consider establishing a wholly owned GPO or using that of another health system as an alternative to the GPOs currently in existence. However, these recent Advisory Opinions underscore the importance of proactive compliance, cost reporting and full disclosure and transparency with respect to discounts, rebates and administrative fees involved in the GPO process.

If you have any questions regarding existing or proposed arrangements that may have AKS implications, please contact:

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