HHS to Audit Hospital Reporting of GPO Payments: GAO Report Suggests Further Scrutiny of GPO Shareback with Hospitals

On November 24, 2014, the Government Accountability Office ("GAO") published a report examining the contracting practices and funding structures of health care group purchasing organizations ("GPOs") and their potential impacts on Medicare spending.[1] The report noted that the predominant GPO funding structure—in which vendors pay administrative fees based on a percentage of the total cost of the products or services sold through the GPO contracts—potentially creates "misaligned incentives for [GPOs] to negotiate higher prices for medical products in order to increase the amount of vendor fees that they receive."[2] However, given the lack of empirical evidence on price impacts, the wide variety of expert opinion on the subject, and the potential short-term disruption to the health care supply chain, the report concluded that a "clearer understanding" of the current funding structure is needed before recommending a repeal of the safe harbor protecting vendor payments to GPOs.[3] Focusing instead on the extent to which GPOs share their revenues with member hospitals ("shareback"), GAO recommended that the Department of Health and Human Services ("HHS") take steps to ensure that hospitals are accurately reporting all revenues received from GPOs on their Medicare cost reports, and HHS concurred with this recommendation.[4] While repeal or significant revision of the GPO safe harbor does not seem imminent, if data gained from HHS's enhanced auditing procedures show that hospitals are not reporting their GPO shareback as discounts, that could provide grist for new Anti-Kickback and False Claims Act enforcement initiatives, either by HHS's Office of the Inspector General ("OIG"), the Department of Justice, or the qui tam relators' bar.

Background: Anti-Kickback Safe Harbors, Reporting Requirements, and Prior Scrutiny of GPOs

Anti-Kickback Safe Harbors

GPOs negotiate contracts with manufacturers, distributors, and other suppliers for the purchase of medical products and services by their health care provider members. GPOs typically receive administrative fee payments from the vendor—"almost always" based on a percentage of the purchase price of the goods or services sold by the vendor under the contract[5]—and pass on at least some portion of these fees to their member providers.[6] Both sets of payments—the payments from vendors to GPOs, and the shareback payments from GPOs to their member providers—potentially implicate the Anti-Kickback Statute's prohibition against "remuneration" intended to induce or reward referrals,[7] but such payments are protected if the requirements of the "GPO safe harbor" and the "discount safe harbor," respectively, are satisfied.[8]

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[1] U.S. Gov't Accountability Office, Group Purchasing Organizations: Funding Structure Has Potential Implications for Medicare Costs (2014), *available here* [hereinafter GAO Report].
[2] *Id.* at 19. *But see id.* at 19-20 (noting that "some experts and representatives of the GPOs" believe that competition between GPOs mitigates any such "theoretical principal-agent problem").
[3] *Id.* at 23.
[4] *Id.* at 23–24, 33.
[5] *See id.* at 16. Among the five largest national GPOs that were the subject of the GAO Report, such administrative fee payments accounted for nearly 92% of all GPO revenue.
[6] *Id.* at 5.
[7] *See* 42 U.S.C. § 1320a-7b(b) (West 2014).
[8] *See* 42 C.F.R. §§ 1001.952(j), (h) (2014).

In order to qualify for protection under the GPO safe harbor, a GPO must: (i) have a written agreement with its members either stating that the fees paid by vendors to the GPO are 3 percent or less of the purchase price of the goods or services sold by the vendor under the contract, or specifying the precise amount (or maximum amount) that each vendor will pay, and (ii) disclose to each of its members at least annually the amount of fees received from each vendor with respect to purchases made on behalf of the member.[9]

The discount safe harbor, meanwhile, imposes requirements on both the recipient and offeror of a discount or rebate, with the specific requirements varying based on the category of purchaser.[10] Hospitals and other institutional providers must, among other requirements, fully and accurately report all such discounts and rebates on their Medicare cost reports.[11]

Previous Scrutiny of GPOs

The GAO report is merely the latest in a series of news articles,[12] reports,[13] and regulatory and oversight activities directed toward the business practices of GPOs and the price impacts of their funding structure.[14] A 2010 report issued by the Senate Finance Committee at the direction of Senator Grassley, for example, declared that—25 years after enactment of the GPO safe harbor provision—"Congress and the American public do not have the data evaluating [its] success or failure."[15] The report recommended legislation authorizing HHS to conduct "an independent and objective analysis [to] assess the true value provided by GPOs to hospitals, and in turn, to the Medicare and Medicaid programs."[16] More recently, HHS's Office of the Inspector General ("OIG") issued an advisory opinion condemning a GPO proposal to offer equity interests in its publicly traded parent corporation to member hospitals, in part because, in contrast to discounts or rebates distributed to hospitals, such equity interests would not be included in hospital cost reports and therefore "would have no potential to benefit payors, including Federal health care programs."[17]

Critical media and regulatory attention notwithstanding, GPOs are a ubiquitous—and growing—component of the health care supply chain. Nearly every hospital in the United States purchases through GPO contracts,[18] while the five GPOs that were the subject of the GAO report collected a total of $2.3 billion in administrative and licensing fees from vendors in 2012, a 20% increase from 2008.[19]

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[9] 42 C.F.R. § 1001.952(j) (2014).
[10] *See* 42 C.F.R. § 1001.952(h) (2014).
[11] *See* 42 C.F.R. § 1001.952(h)(1)(ii) (2014).
[12] *See, e.g.*, Mary Williams Walsh, *Senators Investigate Hospital Purchasing*, N.Y. Times (Aug. 14, 2009), (describing an effort by Senators Herb Kohl, Charles Grassley, and Bill Nelson to "perhaps change or abolish" the GPO safe harbor).
[13] GAO alone issued five reports on GPOs between 2002 and 2012. *See* GAO Report, *supra* note 1, at 3.
[14] *See id.* at 2-3 ("Over more than a decade, members of Congress and others have raised questions about certain GPO contracting practices and the funding structure that includes vendor-paid fees. For example, questions have been raised about sole-source contracting, in which GPOs may contract with only one vendor for a given product when multiple vendors of comparable products are available; product bundling, in which price discounts are linked to purchases of a specified group of products; and long-term contracts of 5 years of more.").
[15] Minority Staff of S. Fin. Comm., 111th Congress, Empirical Data Lacking to Support Claims of Savings With Group Purchasing Organizations 15 (2010), *available here*.
[16] *Id.*
[17] *See* Dep't Health & Human Services, OIG Advisory Opinion No. 13-09 (July 2013), *available here*.
[18] Approximately 96 to 98% of hospitals purchase through GPO contracts, with each hospital using, on average, two to four GPOs per facility. *See* GAO Report, *supra* note 1, at 4.
[19] *Id.* at 17.

GAO Findings and Recommendations

No Consensus and Scarce Data Regarding Price Effects of GPO Safe Harbor

The GAO report found that the funding structure protected under the GPO safe harbor—namely, the payment of administrative fees by vendors based on a percentage of the cost of the products or services sold—"raises questions about whether GPOs are actually negotiating the lowest prices" for their members.[20] GAO's review of literature and interviews with experts, however, revealed no clear answers.[21] The report noted that alternative funding structures are feasible, especially for larger hospital systems that can afford to pay GPO fees or negotiate with vendors directly.[22] Given the uncertainty on prices, however, and the likely short-term disruption to hospitals and vendors, GAO concluded that "a repeal of the safe harbor provision would require a clearer understanding of the GPO funding structure."[23]

HHS Should Take Immediate Steps to Prevent Under-Reporting of GPO Revenues by Hospitals

In contrast to the long-term, indeterminate price impacts of the GPO safe harbor, the possibility that hospitals are failing to accurately and fully account for GPO revenues on their Medicare cost reports presents an "immediate risk [of Medicare overpayment] that can be addressed within the current GPO funding structure."[24] The GAO report found that the extent of this under-reporting problem, if any, is not known, because HHS "has not reviewed cost reports for this information since 2005." Notably, however, the 2005 audit revealed that

> none of the 21 GPO customers . . . fully accounted for revenue distributions they received from the GPOs on their Medicare cost reports—while customers of one GPO offset 92 percent of distributions, customers of another GPO offset only 54 percent. HHS-OIG reported that, in total, the 21 customers offset on their Medicare cost reports $200 million of the $255 million distributed by the GPOs.[25]

In light of these findings, GAO recommended that HHS "determine whether hospitals are appropriately reporting administrative fee revenues on their Medicare cost reports and take steps to address any under-reporting that may be found."[26] HHS agreed, declaring that it will

> add steps to the audit process so that contractors may review Group Purchasing Organization (GPO) administrative fee revenues. There are currently audit steps for contractors to identify rebates,

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[20] *Id.* at 23.
[21] *See id.* ("Some experts believe there is an incentive for GPOs to negotiate higher prices for products and services because GPO compensation increases as prices increase. However, other experts, as well as GPOs, stated that there is sufficient competition between them to mitigate any potential conflicts of interest. Almost 30 years after its passage, there is little empirical evidence to definitively assess the impact of the vendor-fee-based funding structure protected under the safe harbor.").
[22] *Id.* The report cited one example of a large GPO that charges its customers $50,000 per year for access to a web-based system for viewing prices, negotiating contracts with vendors, and tracking purchases and contracts online. *Id.* at 22.
[23] *Id.* at 23.
[24] *Id.* at 23.
[25] *Id.* at 22, n.35. The audit findings prompted CMS to issue a 2011 update to its provider manual specifying that GPO distributions must be properly accounted for on cost reports. *See id.* at 9.
[26] *Id.* at 23–24.

allowances and refunds of expenses (per 42 CFR 413.98), but additional steps will be included specifically for GPOs. It should be noted that expenses are not reviewed on a routine basis for all providers. If expenses are reviewed during the audit process, the contractor will attempt to ensure GPO expenses, if they exist, are reported properly.[27]

Further Scrutiny Ahead?

Some GPO advocates hailed the report as an affirmation by GAO "that the industry can self-regulate and save hospitals money."[28] However, given the persistent scrutiny of the GPO funding structure and its potential impact on federal health care spending, the GAO report at least portends heightened scrutiny of hospitals receiving GPO shareback—which in turn could lead, in the short term, to a new area of Anti-Kickback and False Claims Act enforcement, and in the long run to changes in the safe harbor.

We continue to monitor developments in federal fraud and abuse laws. Should you have questions regarding this Alert, please contact your usual Ropes & Gray advisor.

[27] *Id.* at 33.
[28] *See* Todd Allen Wilson, *GPOs Praise GAO Findings As Validation Industry Can Self-Regulate*, InsideHealthPolicy.com (Dec. 3, 2014).