

Activities and Perspectives of the Office of Inspector General in the U.S. Department of Health and Human Services Regarding Group Purchasing Organizations (GPOs)

Submitted to:

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I. Introduction

The authors of this "White Paper" are Richard P. Kusserow, who served as the DHHS Inspector General from 1980 - 1992, and Thomas E. Herrmann, who served in various capacities in the DHHS OIG Counsel's Office for over 20 years and as an Administrative Appeals Judge on the DHHS Medicare Appeals Council for a six year term. They were requested to conduct an independent and objective historical review of Congressional enactments and DHHS OIG regulations issued over the course of years relating to Group Purchasing Organizations (GPOs). Both individuals were involved with the OIG's endeavors related to GPOs during their tenures with the OIG. Under Mr. Kusserow's direction, the DHHS OIG issued position papers and regulations establishing safe harbors under the AKS and addressing GPOs. This report reflects their professional experience, and personal knowledge and perspectives regarding GPOs.

This report is intended to address issues associated with Group Purchasing Organizations ("GPOs") and their activities in the context of AKS, as well as initiatives over the years by the DHHS OIG. Further, it provides a retrospective review of Congressional enactments and related OIG activities regarding GPOs, and summarizes legislative changes and regulatory issuances relating to GPOs and their impact on Federal health care programs. It explains the relationship of changing Federal health care program payment policies to hospital and other health care providers who use GPOs to purchase equipment and supplies. It also addresses the current safeguards of disclosure, reporting, and transparency for ensuring that GPO transactions do not have an adverse effect on Federal health care programs.

Historically, the Medicare program paid for hospital and nursing home services on a "cost" basis. There was an expectation that costs, as well as any discounts received, would be reported on provider cost reports and reflected in Medicare payment amounts. If hospital costs and discounts were not properly reported, the potential for violating the Federal Anti-Kickback Statute ("AKS") existed.

The AKS is a key Federal statute addressing financial relationships between Federally reimbursed health care providers and suppliers, and manufacturers and suppliers of health care items and services. It is a criminal statute prohibiting the offering, soliciting, payment, or receipt of "remuneration" in exchange for the referral of items and services that may be paid for, in whole or in part, by Federal health care programs, e.g., Medicare and Medicaid.¹ Since the AKS on its face is very broad, concern has been expressed that some relatively innocuous commercial arrangements may be considered to be violations of statute and subject to criminal

¹ Section 1128B(b) of the Social Security Act; 42 U.S.C. § 1320a-7b.

prosecution.² Accordingly, Congress directed the Office of Inspector General ("OIG") in the U.S. Department of Health and Human Services ("DHHS") to develop "safe harbor" regulations "to limit the reach of the statute" and "encourag[e] beneficial and innocuous arrangements."³ GPOs with specified disclosures, reporting, and transparency are an authorized exception under both the AKS, as well as the safe harbor regulations. Recently, questions have been raised about the appropriateness of GPOs with respect to their engagements with vendors and health care providers participating in Federal health care programs.

In summary, the conclusion derived from the review is that as Federal health care programs have moved from reimbursement on a "cost plus" basis to Prospective Payment Systems ("PPS"), fee schedules, and capitated managed care payments, any risks associated with GPOs are addressed through the current statutory and regulatory requirements for disclosure, reporting, and transparency. The mandated disclosure and reporting of cost savings that health care providers achieve through the use of GPOs ensures that Federal health care programs also benefit from lower costs.

II. U.S. Department of Health and Human Services ("DHHS") Office of Inspector General ("OIG")

The OIG was established with a "mission . . . to protect the integrity of DHHS programs, as well as the health and welfare of program beneficiaries."⁴ It operates under the authority contained in the Inspector General Act of 1978, and conducts audits, evaluations, and investigations related to DHHS programs.⁵ As was recently noted by the current DHHS Inspector General, "[s]ince its 1976 establishment, OIG has been at the forefront of the Nation's efforts to fight waste, fraud and abuse in Medicare and Medicaid and the more than 300 HHS programs."⁶ The OIG's jurisdiction encompasses enforcement of the AKS. Over the years, the OIG has conducted investigations, audits, and evaluations, as well as initiated enforcement actions, related to the AKS.

III. Anti-Kickback Statute

The AKS was enacted as a part of the Social Security Amendments of 1972 (Pub. L. 92-603). It has been amended and broadened on several occasions and is currently codified at section 1128B(b) of the Social Security Act ("Act")(42 U.S.C. § 1320a-7b). It has been described as follows:

² See 64 Fed Reg. 63518 (November 19, 1999).

³ 56 Fed. Reg. 35952 (July 21, 1991).

⁴ www.oig.hhs.gov.

⁵ 5 U.S.C. App. 3.

⁶ DHHS OIG Semi-Annual Report to Congress: April 1, 2012 - September 30, 2012.

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by Federal health care programs. . . . Where remuneration is paid purposefully to induce referrals of items or services paid for 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, in cash or in-kind, directly or indirectly, covertly or overtly.

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. *(citations omitted)*⁷

The legislative history indicates that the statute was intended to prohibit "certain practices [that] have long been regarded by professional organizations as unethical, as well as unlawful in certain jurisdictions, and [that] contributed appreciably to the cost of the Medicare and Medicaid programs." These practices included the "soliciting, offering, or accepting of kickbacks or bribes including rebating of a portion of a fee or charge for patient referral, involving providers of health care services."⁸ As explained by the OIG:

The AKS was enacted to address certain risks:

- Arrangements or practices that had the potential to interfere with medical decisions;
- Arrangements of practices that had the potential to increase costs to Federal health care programs and beneficiaries;
- Arrangements or practices that had the potential to increase the risk of overutilization or inappropriate utilization of medical services and supplies; and
- Arrangements or practices that raised patient safety or quality of care concerns.⁹

By enacting the AKS, and various amendments over the years, Congress was seeking to protect Federal health care programs and beneficiaries from the above referenced risks.

⁷ OIG Advisory Opinion No. 12-01 at 5-6, March 8, 2012, www.oig.hhs.gov.

⁸ H.R. Rep .No. 231, 92nd Cong, 1st session 108 (1971).

⁹ OIG Supplemental Compliance Program Guidance for Hospitals, January 31, 2005, 70 Fed Reg. 4858, 4864.

IV. Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977

In 1977, Congress enhanced the AKS through enactment of the Medicare and Medicaid Anti-Fraud and Abuse Amendments of 1977 (Pub. L. 95-142), establishing AKS violations as felonies (as opposed to misdemeanors), broadening the language of the statute to address certain problematic practices, and increasing the penalties. In addition, the Amendments established certain statutory exceptions to the law's broad coverage. These exceptions protected from prosecution:

- Discounts or reductions in price that were "properly disclosed and appropriately reflected in the costs claimed or charges made by [a] provider or entity;" and
- Payments made to employees under a "bona fide employment relationship."¹⁰

Through these amendments, Congress intended to "clarify and restructure the provisions in existing law which defines the types of financial arrangements and conduct to be classified as illegal under Medicare and Medicaid."¹¹ Specifically, with respect to the "discount" exception to AKS coverage," the legislative history noted:

The Committee would encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs.¹²

Through enactment of certain exemptions from AKS coverage, Congress acknowledged the statute's broad applicability, and sought to provide exceptions for practices that posed minimal if any risk. Further, Congress indicated a desire to encourage certain business practices, such as the discounting of prices for health care items and services, where they were passed onto the Medicare and Medicaid programs.

V. OIG Request to the U.S. Department of Justice for "Blanket Declination" of Prosecution of GPOs Under the AKS

In 1985, based on a number of investigations and review, the DHHS Inspector General requested authority from the U.S. Department of Justice ("DOJ") to "inform the public that two increasingly prevalent marketing practices in the health care industry do not warrant prosecution" under the AKS.¹³ One of these practices entailed the use of GPOs. The OIG's request was predicated on the "many inquiries and complaints from hospital suppliers

¹⁰ 42 U.S.C. § 1320a-7b(b)(3)(A).

¹¹ H.R. Report 95-453, 95th Cong., 1st Sess. at 12 (1977).

¹² *Id.*

¹³ Letter from Richard P. Kusserow, Inspector General, DHHS, to Stephen S Trott, Assistant Attorney General, Criminal Division, U.S. Department of Justice, April 17, 1985.

regarding the applicability of section 1877(b) to group purchasing arrangements."¹⁴ The OIG advised DOJ that due to the advent of the Medicare Prospective Payment System ("PPS") for reimbursement of health care providers, the risks associated with GPOs had been significantly reduced.

The OIG represented in its communication to DOJ that "the Department of HHS encourages competitive marketplace strategies in the health sector, including the use of group purchasing agents by hospitals."¹⁵ The OIG further stated that it believed that "the current practice of reimbursement by vendors to group purchasing agents should be permitted." While noting that GPO practices might be a "technical violation" of the AKS, the OIG stated that "the prices of items purchased pursuant to [GPO agreements with vendors] are significantly lower than they would be if each hospital did its purchasing independently because the agent is able to obtain prices based upon large volume discounts."¹⁶

In requesting DOJ immunization of GPO arrangements under the AKS, the OIG noted that the "Department is currently considering legislation to amend [the law] to refine the distinctions between permissible and prohibited arrangements" and set forth its position that GPOs do not add any additional costs to the Medicare program.

The use of volume purchasing through group purchasing agents clearly reduces the costs of purchases by hospitals. Therefore, we would encourage use of such arrangements regardless of the reimbursement methodology. In the case of inpatient hospital care under PPS [Prospective Payment System], any savings which result from volume purchasing accrue to the hospital because Medicare will reimburse a predetermined amount based upon a patient's DRG [Diagnosis Related Group]. In the case of services reimbursed on the basis of cost, the savings from volume purchasing will be passed onto the Medicare program.¹⁷

In its response to the OIG's request, the DOJ declined to "take a public position of cases involving . . . group purchasing agents." It was "not disposed to say that we will not prosecute any cases involving group purchasing agents . . . [as] this would be tantamount to saying that conduct which Congress in its wisdom has made a crime is not a crime." The DOJ recommended that, "if HHS feels that prohibition of the types of conduct described . . . serves no Federal interest and should be allowed, its proper recourse is to the Congress."¹⁸

¹⁴ *Id.* at 4.

¹⁵ *Id.* at 3.

¹⁶ *Id.*

¹⁷ *Id.*

¹⁸ Letter from Stephen S. Trott to Richard P. Kusserow, October 30, 1985.

VI. Amendment to the AKS to Exempt Certain GPO Payments

In 1986, in the Omnibus Budget Reconciliation Act (Pub. L. 99-509), Congress finally addressed the issue of coverage of "Group Purchasing Vendor Agreements" under the AKS. It enacted an amendment to section 1877 of the Social Security Act setting forth certain disclosure requirements that increase transparency and exempt certain amounts "paid by a vendor of goods or services to a person authorized to act as a purchasing agent" for health care providers furnishing services paid for by Medicare. Under the amendment, "remuneration" under the AKS did not encompass:

Any amount paid by a vendor or goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under [Medicare] if:

(i) the person has a written contract, with each such individual or entity which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract; and

(ii) in the case of an entity that is a provider of services, the person discloses . . . to the entity and, upon request, to the Secretary, the amount received from each such vendor with respect to purchases made by or on behalf of the entity.¹⁹

Thus, through amendment of the AKS, Congress expressly permitted GPO arrangements with health care providers and vendors as long as there was an agreement establishing the amounts of any payments made by vendors to a GPO and proper disclosure to DHHS of amounts paid.

VII. The Medicare and Medicaid Patient and Program Protection Act of 1987

In 1987, Congress enacted the Medicare and Medicaid Patient and Program Protection Act ("MMPPPA"), which substantially revised the Federal laws addressing health care fraud and abuse (Pub. L. 100-93). Various provisions pertained to the AKS.

First, Congress acknowledged that certain practices, while technically violations of the AKS, were innocuous business practices that resulted in both efficiency and economy in the delivery of health care services. Congress noted that "the breath of the [AKS] has created uncertainty among health care providers as to which commercial arrangements are proscribed."²⁰

¹⁹ Pub. L. 99-509, section 9321 (Technical Amendments and Miscellaneous Provisions Relating to Parts A and B [of Medicare]).

²⁰ S. Re. No. 109, 100th Cong, 1st Sess. 27 (1987).

Therefore, the Secretary of DHHS was authorized to issue guidance setting forth conduct and practices which would not be subject to prosecution under the AKS. See section 1128D of the Act (42 U.S.C. § 1320a-7d). The OIG was delegated the authority to issue "safe harbor regulations, designed to specify various payment and business practices which, although potentially capable of inducing referrals of business under the Federal and State health care programs, would not be treated as criminal offenses under the anti-kickback statute."²¹ These provisions were to be developed "to limit the reach of the statute somewhat by permitting certain non-abusive arrangements, while encouraging beneficial and innocuous arrangements."²² Any practice or arrangement that met all the requirements of a regulatory safe harbor was deemed to be not violative of the AKS. See section 1128b(b)(3)E(42 U.S.C. § 1320a-7b(b)(3)(E)). In other words, the intent of Congress was to recognize and codify certain beneficial business practices in health care that did not pose risk to either Federal health care programs or beneficiaries, and would not be considered as violations of the AKS.

Second, Congress recognized that an administrative alternative to address violations of the AKS was needed. Therefore, the Secretary of DHHS' authority to exclude individuals and entities from participation in the Medicare and Medicaid programs was amended to establish the alternative administrative remedy of program exclusion for violations of the AKS. See section 1128(b)(7) of the Act (42 U.S.C. § 1320a-7(b)(7)).

And third, broadening the 1986 amendment to Title XVIII of the Act (Medicare), MMPPPA expanded the statutory exception to the AKS' coverage for GPO payments that met certain requirements. Specifically, the AKS was amended to provide that illegal remuneration for purposes of **both** the Medicare and State health care programs did not include:

Any amount paid by a vendor of goods or services to a person authorized to act as purchasing agent for a group of individuals or entities who are furnishing health care services reimbursement under a Federal health care program if:

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services . . . the person discloses (in such form and manner as the Secretary requires) to the entity, and, upon

²¹ Final OIG Rule regarding Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518 (November 19, 1999).

²² 56 Fed.Reg. 35952 (1991).

request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity.

Currently codified at section 1128B(b)(3)(C) of the Act (42 U.S.C. § 1320a-7b(b)(3)(C)).

Some critics of the vendor-based funding model for GPOs have suggested these payments are anticompetitive “kickbacks,” arguing that they may distort a GPO’s purchasing decisions and lead to higher prices as the fees are passed through to the customers. However, Congress rejected these arguments, and legitimized GPOs with specified disclosure requirements and transparency. Congress recognized that under current methodologies for paying health care providers participating in Federal health care programs, potential risks can be avoided with adequate disclosure, reporting, and transparency.

VIII. Other Congressional Enactments Relating to the AKS

In 1996, Congress further amended certain legal authorities for addressing health care fraud and abuse in the Health Insurance Portability and Accountability Act (“HIPAA”)(Pub. L. 104-191). HIPAA extended the reach of the AKS to items and services paid for by any “Federal health care program” (as opposed to the prior “Medicare and State health care programs”). Further, an additional statutory exception to the AKS was established for certain “risk sharing organizations.” Currently codified at section 1128b(b)(3)(F) of the Act (42 U.S.C. § 1320a-7b(b)(3)(F)). Another statutory exception was also established for “waivers of coinsurance obligations” by certain Federally qualified health centers.” See section 1128b(b)(3)(D)(42 U.S.C. § 1320a-7b(b)(3)(D).

Also, recognizing that health care providers and others were seeking guidance regarding the scope and applicability of the AKS, Congress mandated that DHHS provide formal guidance through the issuance of “advisory opinions” in response to requests for advice on whether certain practices and arrangements were violative of the AKS. Section 1128D(b) of the Act(42 U.S.C. § 1320a-7d(b).

And finally, in 1997, Congress authorized another administrative remedy for AKS violations, i.e., civil money penalties, to be imposed by the Secretary of DHHS (through her designee, the Inspector General). Section 1128(b)(7) of the Act (42 U.S.C. § 1320a-7a(a)(7).

IX. OIG “Safe Harbor” Regulations

On January 23, 1989, the DHHS OIG issued a proposed rule establishing “safe harbors” under the AKS, as required by the MMPPPA of 1987.²³ The OIG proposed to establish regulatory

²³54 Fed Reg. 3088 (January 23, 1989A).

standards "to set forth those specific payment practices that would not be treated as a criminal offense under [the AKS] and would not serve as the basis for an exclusion from the Medicare and State health care programs. It was specifically noted that "[i]n order for a business arrangement to comply with one of the exemptions set forth . . . each provision of that exemption must be met." One of the proposed regulatory exemptions amplified on the prior statutory exception to the AKS' coverage of GPOs, and established more detailed standards for disclosure, reporting, and transparency. The OIG stated:

This exemption applies to payments made by a vendor of goods or services to a person authorized to act as a group purchasing organization (GPO) for a number of individuals or entities who are furnishing Medicare or State health care program services. The exemption closely follows the statute, and requires a written agreement between the GPO and the individual or entity that specifies the amount the GPO will be paid. Where the entity is a provider, the exemption requires the GPO to disclose in writing to the provider at least annually the amounts received from each vendor with respect to purchases made on behalf of that provider. Providers must make such disclosures available to the Department upon request, but we are not proposing at this time to require that these disclosures be submitted on a routine basis.²⁴

On July 29, 1991, the DHHS OIG issued its final "safe harbor" regulations, which included a specific safe harbor for GPOs, codified at 42 C.F.R. § 1001.952(j). In order for any payments made to a GPO by a vendor of goods or services to not be considered violative of the AKS, the following regulatory standards had to be met:

- (1) The GPO must have a written agreement with each individual or entity, for which items or services are furnished, that provides for either of the following:
 - (i) The agreement states that participating vendors from which the individual or entity will purchase goods or services will pay a fee to the GPO of 3 percent or less of the purchase price of the goods or services provided by that vendor.
 - (ii) In the event that the fee paid to the GPO is not fixed at 3 percent or less of the purchase price of the goods and services, the agreement specifies 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).

²⁴ Citation to NPRM - Fed. Reg.

(2)Where the entity which receives the good or service from the vendor is a health care provider or 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.²⁵

Implementing the statutory GPO exception to the AKS, the regulation requires that a GPO and the individuals or entities that it represents execute a written agreement that specifies the amount that a vendor will pay the GPO. Further, the GPO must disclose to the entity the fees that it will receive from a vendor that provides equipment or supplies to that entity. The regulation requires that the written agreement between the GPO and an entity specify that the vendor will pay the GPO a fee of 3% or less of the purchase price of the vendor's goods or services, or if the fee is more than 3%, the amount of the GPO payment by each vendor (or if unknown the maximum amount). In addition, with respect to health care providers, the GPO must annually disclose in writing the amount(s) received from each vendor relating to purchases by an entity. These requirements increase transparency by requiring a prescribed level of disclosure between the parties involved in a transaction.

While the OIG has issued various amendments to its "safe harbor" regulations, no changes have been made to 42 C.F.R. § 1001-952(j) pertaining to payments made to a GPO since issuance of the final regulation in 1991. *See* 64 Fed. Reg. 63518 (November 19, 1999).

X. OIG Advisory Opinions

Under its statutory mandate and implementing regulations codified at 42 C.F.R. Part 1008, the OIG has issued a number of Advisory Opinions addressing the appropriateness of various practices and arrangements under the AKS. Several of these Advisory Opinions have related to GPO arrangements.

On September 14, 1998, the OIG issued Advisory Opinion 98-11, reviewing an arrangement between a trade association of nursing homes and a utility consultant who paid fees to the association. The OIG concluded that "in the circumstances presented . . . the fee paid by the Utility Consultant will fit squarely within the GPO safe harbor." Accordingly, the OIG determined that the arrangement would not pose risk to the parties and would not be actionable under the AKS.

²⁵42 C.F.R. § 1001.952(j). The regulation also provides that for purposes of this provision, "the term group purchasing organization (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 or a State health care program, 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)."

On May 22, 2001, the OIG issued Advisory Opinion, 01-06, "regarding payments by vendors to a . . . GPO owned by entities affiliated with various health care providers that purchase items covered by the GPO's vendor contracts. . . ." After summarizing the provisions in the GPO safe harbor (42 C.F.R. 1001.952(j)), the OIG concluded that "[b]ecause all of the GPO safe harbor elements are satisfied, the GPO fees paid by the Vendors to Purchasing Group A would not constitute prohibited remuneration under the anti-kickback statute."

And most recently on March 8, 2012, the OIG issued Advisory Opinion 12-01, regarding a "proposal to establish a . . . GPO that would be wholly owned by an entity that also wholly owns many of the potential participants in the GPO, and to pass through the participants in the GPO a portion of the payments received by the GPO from vendors." The OIG referenced various GAO and OIG audits, reviews, and reports which identified certain "ways in which GPO arrangements can hurt, rather than help, providers and payers." However, it determined that the arrangement presented "an acceptably low level of risk to Federal health care programs."²⁶ Further, it concluded that "although the Proposed Arrangement cannot receive GPO safe harbor protection because the ownership structure of the Proposed GPO, the Proposed Arrangement includes a number of features that mitigate the risks present in some GPO arrangements."²⁷ Therefore, the OIG advised that it would not impose administrative sanctions for any potential violations of the AKS resulting from the proposed GPO arrangement.

XI. OIG Audits

In 2005, the OIG issued two reports relating to audits it conducted of six GPOs "focusing on how much revenue [was] received from vendors and the disposition of that revenue." The audits had similar findings and recommendations.

A report pertaining to a "Review From Vendors at Three Additional Group Purchasing Organizations and Their Members" was issued on May 19, 2005.²⁸ The OIG reviewed how much revenue three GPOs had received from vendors and the disposition of that revenue.

With respect to GPO fee revenue, the OIG found that the three GPOs reviewed had collected \$513 million over a three year period (FY 2001 - FY 2003). Of that amount, \$217 million was distributed to members. The OIG then reviewed the cost reports for 38 hospitals encompassed by seven health care systems that had received a total of \$123 million, or 57% of the \$217 million distributed by the three GPOs. Of these seven health care systems, it was determined that one of them "did not fully account for net revenue distributions on their Medicare cost

²⁶*Id.* at 9.

²⁷*Id.* at 11.

²⁸OIG Audit Report A-0504000073 (May 2005); www.oig.hhs.gov.

reports." Accordingly, the OIG determined that "administrative fees of about \$5 million related to six of the 38 hospitals reviewed were not offset on Medicare cost reports."

With respect to the treatment of rebates received from vendors, the OIG determined that the seven health care systems "received rebates totaling \$115 million directly from vendors or passed from vendors through the GPOs." Further, the OIG's "review of Medicare cost reports for the same 38 hospitals revealed that all GPO members offset rebates on their Medicare cost reports as required." Based on its findings from both audits, the OIG recommended "that clarification of CMS instructions to hospitals is needed." Specifically, it was recommended that CMS:

- Provide specific guidance on the proper Medicare cost report treatment of net revenue distributions received from GPOs and;
- Prepare a "Frequently Asked Questions" or other bulletin to remind institutional providers that all rebates from vendors must be shown as credits on their Medicare cost reports.²⁹

It was reported that, in response to the OIG recommendations, "CMS issued an update to its provider manual specifying that these distributions must be properly accounted for on the cost reports."³⁰

Specifically, the Centers for Medicare & Medicaid Services ("CMS") amended the Medicare Provider Reimbursement Manual "to clarify that discounts or rebates received on a provider's purchases facilitated through a group purchasing organization, or any other returns available by belonging to the organization, are subject to Medicare's policy on discounts, allowances, and refunds."³¹ CMS advised:

A provider is to act as a prudent and cost-conscious buyer in making its purchases seeking to economize by minimizing costs. . . . The prudent provider chooses to either use a GPO or buy directly, whichever results in greater savings.

Although using a GPO generally results in increased discounts or rebates, a provider, as prudent and cost-conscious buyer, is always to seek the greatest available GPO discounts, considering the cost to belong to the GPO and the discounts or rebates it receives on its purchases.³²

²⁹ OIG Audit Report - A-05-03-00074 (January 19, 2005); www.oig.hhs.gov.

³⁰ GAO Report on "Group Purchasing Organizations: Federal Oversight and Self-Regulation, GAO-12-399R (2012) at 10.

³¹ Amendment to Medicare Provider Reimbursement Manual, Part 1 - Chapter 8 (Purchase Discounts; Allowances; Refunds of Expenses), section 805 (Group Purchasing Organizations), Transmittal 450, December 2011.

³² *Id.*

Providers were advised that if they were unable to demonstrate to a Medicare contractor that they had acted as a "prudent purchaser," "costs incurred which are greater than net costs . . . which a provider's contractor finds are reasonably available to the provider, are not reimbursable costs for Medicare purposes."³³

XII. Recent OIG Activities Related to GPOs

Other than the previously referenced Advisory Opinion issued in March 2012, the OIG has not reported on any recent audits or reviews conducted relating to GPOs. It has "participated in two investigations with the DOJ into allegations that certain GPOs did not comply with safe harbor requirements and violated the Anti-Kickback Statute."³⁴ Apparently, both of these cases were initiated by *qui tam* relators under the False Claims Act. In both cases, the DOJ declined to intervene on behalf of the United States.³⁵

XIII. Observations and Recommendations

In the over 25 years since the OIG started reviewing GPO arrangements and activities, a Governmental understanding and recognition of their benefits has developed. The OIG advised the DOJ in 1985 the following:

The Department of HHS encourages competitive marketplace strategies in the health sector, including the use of group purchasing agents by hospitals. Furthermore, under the prospective payment system . . . hospitals have been eager to utilize such cost-saving strategies because the amount they are reimbursed for a patient is predetermined by the patient's DRG.³⁶

Accordingly, with the advent of the Medicare PPS reimbursement methodology, OIG believed that "the current practice of reimbursement by vendors to group purchasing agents should be permitted."³⁷ The OIG recognized the potential cost savings that can be realized through the pooling of purchasing power by GPOs.

Further, as Federal health care programs increasingly moved to PPS forms of reimbursement, fee schedules, and capitated managed care payments, variations in prices offered by vendors have had a reduced impact on the programs' fiscal integrity. On the other hand, to the extent that costs are reported to Federal payers to be used in calculating future PPS and capitated

³³ *Id.*

³⁴ GAO Reportat 9.

³⁵ *Id.*

³⁶ OIG Letter to DOJ, April 17, 1985.

³⁷ *Id.*

rates, any cost savings derived through a GPO needs to be reported by health care providers. The mandated reporting of any cost savings achieved through GPOs by health care providers ensures that Federal health care programs will also benefit from these lower costs in the future. Federal health care program administrators, such as CMS, will need to be vigilant in providing guidance to and oversight of participating providers regarding the reporting of cost savings achieved through the use of GPOs. The heightened attention on program integrity, as mandated by the Affordable Care Act, should help establish comprehensive and timely reporting by health care providers of cost information, including any savings.

The AKS exception for GPOs and "safe harbor" regulations issued in 1991 remain viable in establishing standards for GPOs to meet in order to be immunized from exposure under the AKS. Critical is the requirement for a written agreement between a GPO and health care providers establishing the amount of fees to be paid by vendors. This ensures transparency regarding the terms and conditions associated with payments made by vendors to a GPO. A GPO is required to provide written disclosure at least annually to participating health care providers of the amounts paid by vendors with respect to equipment and supplies that they purchased. Further, HHS is authorized to obtain this information as part of its responsibilities for administering the Medicare program. These safeguards have been incorporated into the OIG's safe harbor regulation addressing GPO arrangements and ensuring disclosure and accountability.

The OIG has been presented with various factual scenarios involving GPOs in recent years. It has been reported that in cases where it has investigated potential violations of law, there has been no further enforcement action. In addition, the OIG has issued several favorable Advisory Opinions regarding proposed GPO arrangements. Critical to legitimizing the most recently reviewed GPO arrangement, the OIG in 2012 based its favorable decision on the goal of achieving lower costs, complete disclosure of administrative fees that would be paid by vendors and "passed through to participants," and the obligation on health care providers "to report the full amount of actual distributions as rebates and net such amounts against the costs of purchases."³⁸ Such disclosure, reporting, and transparency by GPOs and participants in the future will continue to support the integrity of Federal health care programs.

³⁸OIG Advisory Opinion No. 12-01 at 10.