GPO Arrangements Coming Under Government Scrutiny: Are These Harbors Still Safe?

Group purchasing organizations (GPOs) are purchasing agents authorized to act for their members, allowing them to enter into agreements with suppliers or manufacturers through which items and supplies can be purchased by members at competitive prices. Because of their large member base, GPOs may negotiate much more favorable prices with suppliers than individual providers could on their own. Additionally, since GPOs are funded by fees received from suppliers, they are able to furnish these services at little cost to their members.

Although GPOs provide a number of benefits to their members, they have come under fire during the last couple of years. Small medical device manufacturers contend that the GPO industry hampers innovation by foreclosing their access to the market. In response, the U.S. Senate Subcommittee on Antitrust, Competition Policy and Consumer Rights (Antitrust Subcommittee) began conducting public hearings on group purchasing.

Several government agencies, including the Federal Trade Commission (FTC), Department of Justice (DOJ) and Office of Inspector General (OIG) are now in on the action. Government investigators are separately investigating the practices of suppliers and buyers in the medical supply chain. Recently, federal subpoenas were issued to medical supply companies and a GPO in connection with a criminal investigation focusing on whether the GPO misused its market dominance to bundle products and potentially impose other requirements on its customers which the government would consider anticompetitive.

Current Regulatory Oversight

A GPO’s financial relationship and activities raise fraud and abuse and antitrust concerns. From a fraud and abuse perspective, GPOs’ financial relationships with suppliers and members have historically been protected under statutory exceptions to and regulatory safe harbors within the federal Anti-Kickback Statute. Under the antitrust laws, joint purchasing arrangements among health care providers are generally not viewed as anticompetitive, and can achieve protection under DOJ’s and FTC’s antitrust safety zone provision, known as statement 7. In their July 2004 report on competition and health care, DOJ and FTC commented, however, that the safety zone provision of statement 7

U.S. Dramatically Changes ‘Green Card’ Process for Certain Foreign Health Care Workers

On March 28, 2005, the U.S. Department of Labor (DOL) implemented a new program that will significantly change how certain foreign health care workers obtain Permanent Residence status — the coveted “green card.”

For foreign health care workers employed in the United States on the basis of an H-1B visa, the road to obtaining a Green Card to live and work in the United States permanently generally begins with a process known as labor certification.

Through this process, an employer is required to first apply to the DOL for initial certification that hiring an H-1B visa employee on a permanent basis will not take away a job from a like-qualified American worker.

The Program Electronic Review Management System (PERM) program significantly changes the labor certification process. Employers now have the option

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did not protect anticompetitive contracting practices of GPOs.

More recently, the Health Industry Group Purchasing Association (HIGPA), a trade association for GPOs, in consultation with its member organizations, developed a set of principles governing conduct.

A driving force behind the code was a desire for providers to have access to GPOs that offer necessary services at the lowest possible cost, and otherwise encourage ethical and procompetitive business practices. The code addresses a number of areas, including legal compliance, conflicts of interest, use of contracting tools, disclosure of vendor payments and product innovation. A central issue in the hearings before the Antitrust Subcommittee is whether the safe harbors under the federal Anti-Kickback Statute and the code are sufficient controls for the GPO industry to police itself.

**Federal Anti-Kickback Statute**

Two payment streams in the GPO-medical supply chain implicate the federal Anti-Kickback Statute and necessitate safe harbor protection. First is the administrative fee a GPO receives from suppliers for the GPO’s services. If properly structured, these arrangements can achieve protection under the group purchasing organization safe harbor. The second payment comes in the form of a discount or rebate and is generally provided to the GPO member. The discount or rebate can be provided by the supplier or GPO (or both) to the GPO member and, again, if structured properly, can achieve protection under the discounts safe harbor.

**Safe Harbors**

**Group Purchasing Organizations**

Since GPOs can refer business to suppliers (through their negotiation of contracts for the benefit of their members) and receive an administrative fee in return for these services, a GPO’s arrangement with a supplier implicates the federal Anti-Kickback Statute. These fees represent the bulk of a GPO’s revenue, so protection of these arrangements is critical to a GPO’s financial survival.

The group purchasing organization safe harbor protects (under certain circumstances) administrative fees from a supplier to a GPO. Specifically, for purposes of the federal Anti-Kickback Statute, “remuneration” does not include any payment made by a supplier of goods or services to a GPO, as part of an agreement to furnish such goods or services to an entity or individual, as long as both of the following two standards are satisfied:

- The GPO must have a written agreement with each entity or individual for which items or services are furnished, that provides for either of the following:
  - Participating suppliers from which the entity or individual 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 supplier.
  - 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 or services, the agreement specifies the amount (or if not known, the maximum amount) each supplier will pay to the GPO (where such amount may be a fixed sum or a fixed percentage of the value of purchases made from the supplier by the members of the group under the agreement between the supplier and the GPO).

- If the entity that receives the goods or services from the supplier is a health care provider of services, the GPO must disclose in writing to the entity at least annually, and to the Department of Health and Human Services (HHS) upon request, the amount received from each supplier with respect to purchases made by or on behalf of the entity.

This safe harbor is under attack for failing to keep suppliers and GPOs with significant market share from entering into lucrative long-term arrangements that would keep small suppliers out of the market. The Medical Device Competition Act of 2004, which was recently introduced in Congress, would (if approved) amend the current GPO safe harbor. Specifically, the legislation would require:

- the amount paid by the supplier to a GPO cannot exceed a total of 3 percent of the purchase price of the goods or services provided by the supplier; and
- the GPO’s contracting, business and ethical practices must be consistent with the regulations promulgated by the Secretary of HHS, and the GPO must be certified to be in compliance with those regulations.

Additionally, the legislation would amend the federal Anti-Kickback Statute to require the

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Secretary of HHS to consult with the Attorney General and FTC and issue regulations that must specify contracting, business and ethical practices of purchasing agents that would be contrary to antitrust law, ethical standards or the goal of ensuring that products necessary for proper patient care or worker safety are available to physicians, health care workers and patients. Significantly, the Secretary also would be required to consult with the FTC and Attorney General to issue regulations to clarify that the remuneration paid to GPOs and protected under the existing safe harbor would include only reasonable costs associated with the procurement of products and the administration of valid contracts and would exclude marketing costs, extraneous fees or any other payment intended to unduly or improperly influence the award of a contract based upon factors other than cost, quality, safety or efficacy. Clearly, this could have a detrimental impact on the financial success of GPOs.

The second payment stream under attack is the discounts and rebates provided to GPO members.

Discounts
Discounts implicate the federal Anti-Kickback Statute because they are viewed as “remuneration” or “value” being transferred to a provider (a potential referral source) who is in a position to purchase or arrange for the purchasing of items or services from the entity providing the discount. Just as the regulations to the Anti-Kickback Statute afford safe harbor protection to certain GPO arrangements, safe harbor protection exists for certain discounts to GPO members (or buyers) who enter into contracts with offerors and sellers of health care goods and services. These discounts give an offeror or seller the ability to provide buyers with more competitive pricing.

For purposes of the safe harbor, the term “discount” means a reduction in the amount a buyer (who buys either directly or through a wholesaler or a GPO) is charged for an item or service based on an arms-length transaction. A discount also includes a rebate, which is any discount the terms of which are fixed and disclosed in writing to the buyer at the time of the initial sale to which the discount applies, but which is not given at the time of sale. The term discount does not, however, include cash payments or cash equivalents (except for appropriate rebates), bundling of products (with some exception), a reduction in price not applicable to federal health care programs, routine waiver of any coinsurance or deductible amount, warranties, and services provided in accordance with a personal services or management services contract.

The discount safe harbor focuses on the disclosure and reporting obligations of the parties involved in these transactions, including buyers, offerors and sellers. For purposes of the safe harbor, a GPO’s members would be considered buyers, the GPO, an offeror, and the supplier, a seller.

Buyer Obligations
If the GPO member (or buyer) is a cost-reporting entity, such as a hospital, the discount must be earned based on purchases of the same good or service bought within a single fiscal year of the buyer, and the buyer must:

- claim the benefit of the discount in the fiscal year in which the discount is earned or the following year
- fully and accurately report the discount in the applicable cost report; and
- provide, upon request, the information regarding the discount to HHS or state health care program, as provided to the buyer by the offeror or seller, as the case may be.

If the buyer is an entity or individual in whose name a request for payment is made, and payment may be made to that buyer under the federal health care programs, the discount must be made at the time of sale of the good or service or the terms of the rebate must be fixed and disclosed in writing to the buyer at the time of the initial sale of the good or service, and the buyer must provide, upon request, the information regarding the discount to HHS or state health care program as provided to the buyer by the offeror or seller, as applicable.

Offeror Obligations
GPOs (as offerors) and suppliers (as sellers) can provide discounts to GPO members. The requirements of an offeror under the GPO safe harbor are substantially similar to those of a seller. An offeror of a discount is an individual or entity which is not a seller but promotes the purchase of an item or service by a buyer. If the GPO member or buyer is a cost-reporting entity or an entity in whose name a request for payment is submitted for the discounted item or service, and payment may be made under the federal health care programs, the offeror must:

- inform the buyer (or individual or entity submitting the claim) of its obligation to: (a) report the discount; and (b) provide the discount information upon request to HHS or state health care program; and
- not act in a manner that would impede the buyer from meeting its disclosure obligations.

Critics argue these disclosure and reporting requirements are insufficient to protect against potentially abusive or anti-competitive activity. Government officials are investigating whether fees, rebates and discounts provided by suppliers and GPOs to providers are being accurately reflected in costs charged by providers to the federal health care programs. Accurate reporting of such rebates and discounts is also an area of review under OIG’s 2005 work plan.

Supporters, however, contend that these safe harbors are sufficient and protect legitimate business arrangements that are crucial to the
Accordingly, the critical issue for manufacturers and GPOs would be whether supplier payments to GPOs must be included in the ASP calculation since they, too, affect the price actually realized by the manufacturer. If so, the issue of whether these payments will continue to be protected under the GPO safe harbor or be considered a discount under the discounts safe harbor would have to be addressed (although the discounts safe harbor would not technically apply since a GPO is generally not a buyer of goods and services).

Potential also exists for suppliers to restructure their administrative fee arrangements with GPOs, since any administrative fee paid to GPOs would lower the suppliers’ ASP, which could lower the reimbursement of its pharmaceuticals under the government programs, negatively affecting a supplier’s revenues.

Given the activity surrounding GPOs and their arrangements and business practices, it is clear that some form of action will be taken that will affect the business of GPOs in the future. At the conclusion of its hearings, the Antitrust Subcommittee suggested alternative approaches to regulating the GPO industry. Changes could include tighter regulation and amendment of the GPO safe harbor, HHS taking a more active role in regulating the industry, codification of industry guidelines and certification (of the legitimacy of the contracting and other practices of GPOs) by an accrediting body or special counsel in FTC or DOJ.

Some steps have already begun at the legislative and administrative levels, including activity in Congress that would affect the current scope of coverage of the GPO safe harbor. It remains to be seen, however, which approaches will be implemented and whether the arrangements GPOs have with suppliers and members will continue to be safe or will need to be restructured in some fashion to comply with federal fraud and abuse and antitrust laws.

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of submitting applications for labor certification electronically and directly to a national processing center of the DOL. This is a change from the “old” system, which required numerous paper forms to be mailed to local offices of the DOL for initial processing.

PERM also generally eliminates the requirement that employers submit considerable supporting documentation along with the labor certification application. The goal of these and like changes is to reduce the current backlog (years) of labor certification cases pending with the DOL.

While PERM has inherent benefits for employers, the process is not without added costs. To use the PERM process, employers must do more “back office” work than under the old system. For example, employers will have to do more recruiting than needed before PERM to show that no sufficient United States workers are able, willing, qualified and available as required by the labor certification process. As part of this recruiting process, employers will no longer be able to use “blind ad” recruiting – employers must list their name in the newspaper advertisements generally used as part of the labor certification recruiting phase. In addition, employers must pay an employee 100 percent of the prevailing wage required by the DOL for the job being performed by the foreign national health care worker. Before PERM, payment of 95 percent of this prevailing wage was permitted.

The implementation of PERM has long been anticipated by the health care community as a welcome improvement in the process to assist foreign nationals in obtaining green cards. The reduction in the processing times for labor certification should significantly assist employers in retaining their most valued foreign national employees on a long-term basis.

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New Jersey Court Refuses To Enforce Restrictive Covenant In Psychologist’s Employment Contract


The plaintiff, Comprehensive Psychology Systems, P.C., provides professional neuropsychological services to individuals under the name LifeSpan. Comprehensive sought to enforce a restrictive covenant in the employment contract of defendant Brett Prince, Ph.D., a licensed psychologist formerly employed by Comprehensive. The contract contained a restriction that, after two years following the termination of the agreement, the licensee may not participate in offering or employing any other Comprehensive employee. The covenant also barred Dr. Prince from practicing within 10 miles of Comprehensive’s facility for two years.

Central to both the trial court and appellate court’s decision not to enforce the covenant was N.J. Admin. Code §13:42-10.16, a provision of the rules adopted by the Board of Psychological Examiners governing restrictions placed on the practice of licensed psychologists.

The trial court found the covenant unenforceable and refused to restrain Dr. Prince from contacting any patients or contacting referral sources. In so holding, the trial court reasoned that under NJAC 13:42-10:16, a licensee may not participate in any employment agreement that restricts the right to practice the licensed profession after termination of employment, and that the agreement at issue violated this rule. Comprehensive appealed the decision.

Relying on the principles set forth in Karlin v. Weinberg, 77 N.J. 4 (1978), Comprehensive argued that the restrictive covenant at issue was enforceable against Dr. Prince. According to Comprehensive, the trial judge misconstrued the language of the NJAC 13:42-10:16 which, properly interpreted, permits the type of non-competition agreement entered into by Dr. Prince and Comprehensive. Alternatively, Comprehensive argued that the regulation, as amended on April 5, 2004, allowed non-compete agreements restricting the practice of a licensed psychologist. The amendment reads:

“The licensee shall not enter into any business agreement that interferes with or restricts the ability of a client to see or continue to see his or her therapist of choice.” NJAC 13:42-10:16.

The appellate court declined to apply Karlin, finding it distinguishable from the situation in this case. In Karlin, the New Jersey Supreme Court rejected a per se rule of unenforceability, holding that restrictive covenants ancillary to employment contracts between physicians are enforceable to the extent that they protect a legitimate interest of the employer, impose no undue hardship on the employee and are not injurious to the public. Id. at 411-12. The appellate court rejected Comprehensive’s argument that, although Dr. Prince was not a physician, the principles of Karlin should apply equally to a psychologist, and the non-compete should be upheld. The court reasoned that Karlin only applies to general covenants in situations where applicable regulations do not exist, so it did not apply to agreements restricting the practice of licensed psychologists.

The court found the holding of Dwyer v. Jung, 133 N.J. Super. 343 (Ch. Div. 1975), analogous to the Comprehensive case. In Dwyer, the court held that because of the personal, highly fiduciary nature of the attorney-client relationship, restrictive covenants between attorneys are per se unreasonable and unenforceable as injurious to the public interest. Id. at 346-47. The appellate court reasoned that the regulations governing psychologists were similar to the regulations governing attorneys in Dwyer, since both regulations were intended to restrict individuals in the respective professions from entering into restrictive covenants.

The Comprehensive court also found that the language contained in the April 2005 amendments to N.J.A.C. §13:42-10.16 would not permit the enforceability of a restrictive covenant against a psychologist.
Rather, “the new regulation merely articulates
the same restriction in language that shifts
the focus of concern from the rights of the
psychologist to the rights of the patient.”
*Price*, at *6. Finally, the court noted that a
psychologist who changes his office locations,
voluntarily or involuntarily, has a duty to
inform patients of the change and the new
location and phone number. To do other-
wise, the court concluded, would be akin to
patient abandonment.

The *Comprehensive* decision serves as yet
another reminder to New Jersey employers in
the health care field of the difficulty in
protecting their legitimate business interests.
Patient rights in this area will be given greater
weight than the rights of employers to
restrain former employees from competing in
the marketplace. In the future, it appears
unlikely that a New Jersey court will enforce
a non-compete contained in an employment
agreement that in any way alters or impinges
on a psychologist’s right to treat patients or a
patient’s right to continue to seek treatment
from a particular psychologist.

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