



**THE PERFORMANCE OF GROUP PURCHASING ORGANIZATIONS (GPOs)
IN THE HEALTH CARE VALUE CHAIN: A LITERATURE REVIEW**

Lawton Robert Burns, Ph.D., MBA
The James Joo-Jin Kim Professor
Department of Health Care Management
The Wharton School
University of Pennsylvania
3641 Locust Walk
Philadelphia, PA 19104-6218
PH: 215-898-3711
FAX: 215-573-2157
burnsL@wharton.upenn.edu

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Executive Summary

Group purchasing organizations (GPOs) have existed in the U.S. for over a hundred years. They came to prominence during the last quarter of the twentieth century as they steadily aggregated the purchasing of hospitals. By the start of the new millennium, GPOs increasingly came under challenge for their contracting performance and the value they rendered to both hospitals and society.

This report reviews the academic literature and evidence base for these challenges. The report documents that the allegations about GPOs that surfaced in a series of *New York Times* articles and Senate Hearings are without foundation. In fact, the evidence suggests that group purchasing is a strategic tool used worldwide in both public and private sectors. It is also a strategic tool that is used differently by different types of hospitals, thus requiring a joint analysis of both GPOs and hospitals to gauge its effects.

Specifically, the report finds that GPOs help hospitals to achieve lower product prices. GPO prices may not be the lowest prices observed, however, given some hospitals' effort to negotiate further discounts using the GPO price. When aggregated across hospitals, the price discounts obtained through GPO contracting can lower both hospital costs and national spending. The report also finds that the fees that GPOs charge suppliers have averaged around 1-2 percent of contracted purchases, much lower than what was reported years ago, and that a majority of these fees are rebated back to hospital members.

With regard to contracting practices, GPOs have diminished their use of sole-source and bundled contracts. However such practices are still popular among their hospital members; moreover, such practices are also used in the procurement practices of the U.S. Government. GPOs provide a host of other services to their members, including clinical review processes, e-commerce solutions, benchmarking, and technology assessment.

GPOs have also developed codes of conduct with external scrutiny to provide greater transparency to their operations and accountability to their members and society.

The GPO marketplace is competitive, with substantial rivalry not only among the handful of large national GPOs but also with the growing number of regional and local GPOs. GPOs not only compete with one another but also foster competition in supplier markets for GPO contracts. There is little evidence that GPO contracts have excluded smaller and innovative suppliers from the market. In fact, the evidence suggests that GPOs improve hospital awareness of new products and technology. Overall, hospitals have been consistently satisfied with the services provided by GPOs, as reflected in their historical reliance on and membership in multiple GPOs.

Hospitals now face reimbursement cuts from public payers and an increased need to lower costs to meet value-based payment requirements. GPOs and improved supply chain management offer hospitals perhaps their single best opportunity to meet these challenges.

THE PERFORMANCE OF GROUP PURCHASING ORGANIZATIONS (GPOs) IN THE HEALTH CARE VALUE CHAIN: A LITERATURE REVIEW

Introduction

Group purchasing organizations (GPOs) evolved gradually over the course of the twentieth century from grassroots efforts typically led by state hospital associations. GPO growth accelerated in the last two decades of the past century, aided by the formation of both investor-owned and nonprofit multi-hospital systems, enactment of the prospective payment system (PPS) for inpatient hospital reimbursement, and the rise of managed care organizations (MCOs). Hospital combinations often prompted GPO combinations in order to offer scale economies in purchasing to the increasingly large hospital groups. Such efficiencies became more important for hospitals due to the cost containment pressures exerted by PPS and MCOs.

GPO growth manifested itself both in terms of the number of hospitals participating in GPOs and the size of GPO membership rosters. By the end of the century, the vast majority of hospitals contracted with vendors in the marketplace for supplies in a collaborative fashion through a small number of large GPOs.¹

At the same time, in 1982, Paul Starr published his seminal work on the history of the U.S. medical profession.² The book described how physicians (and providers in general) had come under attack in recent years for the cost and quality of the care they rendered. Such attacks came in the form of “performance challenges” (were physicians and hospitals practicing medicine in an efficient manner, or were they engaged in wasteful overutilization and duplication of services?) and, more importantly, “value challenges” (were physicians and hospitals providing added quality for all of this spending, and were they acting according to ethical standards and in society’s interest?). Much of the concern was prompted by fee-for-service reimbursement payments (made by Medicare and Medicaid, as well as by private insurers), the resulting rise in costs and utilization, and the corporatization of health care using business strategies of horizontal consolidation, vertical integration, diversification, service line management, and revenue maximization.

Performance and Value Challenges to GPOs

While similar challenges to GPOs were hinted at in the late twentieth century, full-blown challenges arose in the early twenty-first century.³ Beginning in 2002, GPOs came under intense scrutiny, investigation, and criticism. On the performance side, GPOs were suspected of not obtaining the lowest prices for hospital members in their contracting processes; on the value side, GPOs were thought to have the opposite incentive of allowing vendors to charge high prices that would net the GPOs higher contract administration fees (CAFs). That is, GPO contracts were designed to serve the suppliers' and GPOs' financial interests rather than (a) save hospitals money on supply purchases and (b) save society money in the form of lower costs for Medicare and Medicaid patients treated at these hospitals. Such concerns went beyond cost and extended to quality. GPO contracts with large suppliers were allegedly to blame for keeping smaller and potentially more innovative suppliers out of the market, thereby serving as a barrier to patients' access to novel technologies that could potentially save lives.

A long series of articles appearing in the *New York Times* between March and December 2002 marked the first salvo.⁴ The *Times* articles claimed that GPO contracts with large suppliers benefited the GPOs at the possible expense of member hospitals, physicians, and patients. GPOs could earn 3% CAFs on contracts they negotiated with suppliers - - fees legitimated by the DHHS safe harbor provisions. But, according to the *Times*, GPOs kept these fees rather than passed them on to their members. Moreover, smaller supply firms were often characterized as unable to afford such fees, which limited their ability to get GPO contracts and thus get their products in front of physicians and their patients. Small suppliers were also excluded by the GPOs' use of sole-source contracts with one large vendor (or dual source contracts with two large vendors). Such contracts routed a large volume of hospital purchases (and thus, fees) through one or two supplier contracts with the GPO. Small vendors that lacked the manufacturing scale needed to supply these large national contracts were thus excluded.

Prompted by these concerns, academics began to conduct research that examined such issues. Proponents and opponents of the GPOs likewise sponsored a series of white papers and expert reports to advance their claims regarding GPO performance and value - not only in press releases but also in litigation proceedings. These research studies and reports had little to build upon; the 1990s had produced only a smattering of research studies regarding GPOs or group purchasing, most of which were small-scale in scope. Finally, the U.S. Government became interested in these issues, manifested by four Senate Judiciary Committee Hearings on GPO contracting practices (see Appendix I) and a series of GPO performance audits requested by the Senate and conducted by the Government Accountability Office (GAO). Many of the critics and detractors of these practices called on the Senate to repeal the safe harbor for GPOs (see footnote 3).

The Senate Hearings and reports surfaced four major issues. One recurring issue was whether large GPOs' contracts with large suppliers excluded smaller supply companies and their innovative products from the market. A related issue concerned the length of these GPO-supplier contracts (mostly 3-year, some 5-year), which might exclude small suppliers from the market and starve them of business. GPO contracts could thus reduce competition and inhibit incentives for small innovative companies to enter the market. A third issue was whether GPOs actually provided better pricing and value to their hospital customers and thereby warranted protection for the fees they charged suppliers under Medicare's safe harbors. A fourth issue was the financial relationships (and the potential for conflicts of interest) between the GPOs and large vendors.

To date, the discussion has largely been driven by (a) charges of misconduct leveled against the GPOs by small device manufacturers who took their complaints to the media, the Senate, and the courts, (b) the small manufacturers' trade group (Medical Device Manufacturers Association, or MDMA), (c) a vigorous defense of GPO practices by the industry's trade organizations (Health Industry Group Purchasing Association, or HIGPA; later renamed the Healthcare Supply Chain Association, or HSCA, as the GPOs'

functions broadened from purchasing to sourcing and quality initiatives), and (d) supporting evidence rendered by outside experts solicited by each side.

Perhaps the most surprising contribution to the GPO debate occurred in March 2006 at the end of the final Senate Hearing. Committee member Senator Schumer (D-NY) recast the role of GPOs from “agents of suppliers” (as GPO critics alleged) to “agents of hospitals” who helped them to negotiate with the wealthy manufacturers. One of the few things hospitals could do to save money is to band together to buy supplies in bulk, and GPOs played an instrumental role in this process. Unfortunately, Congress did not allow Medicare to bargain in the same way with pharmaceutical manufacturers, which cost the public money. The idea that hospitals would want to pay more money for supplies to feather the nest of the GPOs made no sense. Finally, he suggested the self-regulatory approach undertaken by the GPOs was working, that the HGPII made sense, and that a large number of organizations were participating in it. Senator Schumer stated he would need evidence to the contrary before supporting any regulatory or legislative approach (see Appendix I) to reform GPO practices.

Organization of the Report

Any effort to summarize the literature on GPOs and group purchasing in general needs to be placed in this context. The literature consists of a handful of academic studies, a larger number of industry-sponsored reports either pro-GPO or anti-GPO, the GAO analyses, and a host of trade magazine and newspaper articles.

This literature review is organized as follows. We summarize the results of the academic research and industry-sponsored studies that speak to the issues and arguments raised in the Senate Hearings. We conclude by summarizing the evidence base on GPO performance as it speaks to the performance and value challenges laid at the feet of the GPOs.

The literature reviewed below limits itself primarily to the U.S. academic research and industry-sponsored studies on GPOs utilized by hospitals. We do not consider physician-owned GPOs, which have existed for more than two decades and have become quite controversial.^{5 6} We also acknowledge that group purchasing is a global phenomenon that is not confined to the U.S. (covered later below). Finally, we need to avoid any tendency to homogenize the GPOs or treat them as a monolithic group. Indeed, research highlights the diversity in GPO structure and function (i.e., their history, formation, ownership, governance, contracting practices, etc.), the variability in their performance and member satisfaction, and the variability in their customers.^{7 8} Such variability is often forgotten and neglected in the GPO debate.

Academic and Industry Studies

GPO Operations and Strategy

Prior to the first Senate hearing in 2002, Wharton School researchers published an analysis of the U.S. health care industry that included a discussion of the role of GPOs in the supply chain, as well as GPO operations and strategy.⁹ The analysis was thus not colored by the issues and rhetoric that prevailed during the hearing and the *Times* articles.

The analysis considered the relationships GPOs have with suppliers upstream and hospitals downstream, as well as GPO efforts to develop strategic capabilities in clinical standardization, product (stock-keeping unit, or SKU) rationalization, product bundling, and reductions in both costs and utilization. The latter efforts met with only mixed success. Utilizing a mixture of interviews and case studies, the study offered an objective view regarding how GPOs functioned and how well they served the welfare of their hospital members. The Wharton study suggested that while GPOs sought to serve the hospitals' interests, their national scope and size limited their ability to represent the interests of their numerous, diverse members. Their performance was also constrained by the ability of hospital systems and integrated delivery networks (IDNs) to contract with suppliers on their own. In light of the criticisms leveled at the GPOs during the Senate

hearings, the lead researcher looked back and concluded that “GPOs are not as good as they think they are but are not as bad as their critics say they are”.¹⁰

Four years later, researchers at Arizona State University published a second analysis of the supply chain in health care.¹¹ The authors argued that GPOs served as an important partner in hospitals’ efforts to manage their procurement processes, reduce their cost of operations, and improve the clinical outcomes of their patients. The study was also quite clear in stating that GPOs served the interests of hospitals, not the suppliers. Hospitals had very measured strategies for utilizing their GPOs and often engaged suppliers in the marketplace on their own for both GPO-contracted and non-GPO-contracted products. They identified four types of GPO engagement by hospitals:

Type 1 - GPO dominated purchasing: high GPO involvement in product selection and high use of GPO contracts.

Type 2 - Strategic outsourcing of contracting: low GPO involvement in product selection and high use of GPO contracts.

Type 3 - Strategic manipulation of purchasing: high GPO involvement in product selection and low levels of GPO contracts.

Type 4 - Hospital/IDN dominated purchasing: low involvement of GPO in product selection and strategic sourcing and low use of GPO contracts.

The reason why these four different types of engagement existed was the heterogeneity in both the GPOs and their hospital members. Hospitals chose GPOs on the basis of fit with their needs and capabilities, including the possible presence of GPO demands for committed contracting. This analysis recast the debate from how GPOs behaved (where much of the rhetoric in the press and Senate hearings focused) to how hospitals behaved in their use of GPOs.

Hospital Prices: The Evidence Base

Accompanying and supporting the first Senate hearing was a report released by the General Accounting Office (GAO) on the GPOs' contract prices obtained for 18 hospitals in one geographic market for medical devices (e.g., pacemakers).¹² The April 2002 report compared the prices obtained by GPOs with the prices that hospitals negotiated on their own.¹³ The report found that use of GPO contracts did not always guarantee the lowest prices for their hospital members, although the pattern varied by product category. For some pacemakers, hospitals beat the GPO price by 39%; for other pacemaker models, the GPO contract prices out-performed hospital-negotiated contract prices by 26%. Price savings had no relationship to GPO size; large GPOs with large volume purchases did not always get lower prices. Savings were related to hospital size, however: larger hospitals (500+ beds) could negotiate lower prices on their own, while smaller hospitals were more likely to obtain lower prices using GPO contracts.

A July 2003 GAO report specified some of the factors involved in obtaining lower pricing.¹⁴ For the five smaller GPOs queried, hospital adherence to contract commitment levels was the most important factor in obtaining favorable supplier pricing; for the two large GPOs queried, volume was the most important factor.

A 2009 report issued by academic researchers at Arizona State University suggested one reason why GPO prices were not always the lowest price that hospitals could obtain.¹⁵ In a survey of 429 hospitals in 55 hospital systems, 35% of hospitals and 42% of systems indicated they used the GPO contract as a starting point (e.g., price ceiling) in their negotiations with manufacturers. This percentage varied for different types of products, being less likely for pharmaceuticals (29-35%) and commodity items (33-44%) and more likely for capital equipment (40-52%) and PPIs (50-57%). These percentages reflected the fact that respondents did not perceive GPO prices as being the lowest prices across all product categories. When asked to rate the GPO's role in obtaining the lowest price using a five-point Likert scale (1=not at all important, 5=extremely important), respondents gave the GPO the highest rating for commodity items (4.9) and

pharmaceuticals (4.9), but lower ratings for PPIs (3.6). Within the PPI category, hospitals utilized GPO contracts and GPO pricing to greater or lesser degrees depending on the sub-category of products. GPO contracts were more heavily utilized for stents (29%) than for orthopedic implants (19%) or pacemakers (16-17%); hospitals were more likely to use the GPO price as a “reference price” for orthopedic implants (15%) than for stents and pacemakers (8%), and more likely to use GPO price as a “benchmark” for orthopedic implants (23%) than for stents or pacemakers (20-21%).

A 2003 report by The Lewin Group, conducted for HIGPA, surveyed materials managers about the financial benefits offered by their GPOs.¹⁶ As suggested by the Arizona State University research, the Lewin Group found that 82% of respondents perceived GPO prices as “benchmarks” or price ceilings, below which hospitals might negotiate even lower prices. Price discounts on product purchases represented the majority of these benefits, accounting for 7.72% savings on purchases; an additional 1.85% savings was provided by dividends received from GPOs, along with another 0.84% savings on labor staffing. When asked what would happen if GPOs were absent, 90% of hospitals responded that prices would rise; 7 percent said there would be no change in prices, and another 2 percent were unsure. Qualitative remarks suggested that hospitals felt suppliers would regain control of the negotiating process and that products might revert to (higher) list prices. Hospitals also felt they would have to add staffing to compensate for the functions performed by the GPOs.

Most of the literature on price savings obtained through GPO contracts is based on survey responses from hospital purchasing managers and anecdotal reports. Only two of the studies were peer-reviewed.^{17 18} Moreover, many of the studies reporting the savings were funded by the GPO industry itself or by critics of the GPO industry (e.g., MDMA).

To ascertain the quality of the evidence base, members of Congress requested the GAO to review the literature regarding the impact that GPOs exerted on pricing.¹⁹ The GAO located only one of the peer-reviewed studies published in the academic literature. That

study conducted a national survey of hospital materials managers, who reported that GPOs saved them money on product prices, reduced transactions costs, and improved revenues through rebates and dividends.²⁰ That study received subsequent validation by another national survey of hospital managers (chief financial officers, directors of materials management, etc.) in 2010 that indicated high satisfaction with GPOs for their pricing and savings.²¹ Nevertheless, a Minority Report from the U.S. Senate Finance Committee emphasized, as did the GAO study, the lack of empirical data to substantiate claims that GPOs helped their hospitals to save money.²²

In a more recent effort to investigate this issue, two consultants (and critics of the GPO industry) analyzed 8,100 after-market transactions for capital equipment in which the winning GPO price was put up for bid after the initial GPO auction.²³ On average, hospitals achieved 10-14% savings over the period 2001-2010, suggesting that GPOs did not secure best pricing for their hospital members. The paper is consistent with evidence reviewed above that hospitals could often obtain better pricing than their GPOs, particularly when using the GPO price as the ceiling or benchmark from which to negotiate additional discounts. However, the paper did not study GPO prices but rather the discounted pricing from auctions - - which was comparable to what hospitals obtained when negotiating on their own. The fact that auction prices were lower than GPO prices failed to address what GPOs did or did not achieve for their members. Moreover, the paper suffered from a methodological flaw of commingling several different product categories that have greater or lesser degrees of GPO market penetration.

An interesting set of case studies conducted as part of a Masters Degree thesis compared the costs of product procurement across three models: self-procurement by hospitals, use of a national GPO, and a hybrid approach that combined use of a national and a regional GPO. The study found that use of the national GPO outperformed hospital self-contracting, but that a hybrid approach led to additional savings. Similar findings were reported for the breadth of products and presence of products with innovative features.²⁴

Finally, several recent government and academic studies shed further light on why hospitals and their GPOs vary in their ability to obtain lower pricing for medical devices (the subject of the April 2002 GAO report). A 2012 GAO report found that hospitals paid widely varying prices for cardiovascular and orthopedic implants.²⁵ The GAO concluded that a major source of the variation rested with the hospitals' ability to manage their relationships with physicians. The hospital's ability was a function of the number of specialists whose preferences needed to be considered, the dollar volume each specialist accounted for and the referral volume each specialist generated, the specialists' ties to the suppliers, and the presence of confidentiality clauses imposed by suppliers on the hospitals which prevented the latter from sharing price information with physicians. Researchers at the University of California reported similar results on pricing variations due to physician-hospital relationships.²⁶ Both studies were consonant with the theoretical arguments outlined in an earlier academic paper as to why pricing variations existed and why mandated price transparency would not reduce them.²⁷

Value of Group Purchasing

One issue related to best pricing is whether or not GPOs deliver value in the aggregate to their hospital members. Such 'value' is often measured in terms of the overall savings that GPOs can provide. One early report conducted at Arizona State University (ASU) utilized case study evidence collected by Novation, the GPO contracting for hospitals in the University Hospital Consortium (UHC) and Voluntary Hospitals of America (VHA). The case studies were based on interviews with and data collected from department managers in 55 hospitals in ten hospital systems. The report compared the cost of self-contracting by hospitals with the cost of GPO contracting.²⁸ Hospital-led efforts incurred a cost of \$3,116 per contract compared to GPO-led efforts of \$1,749 per contract, suggesting a savings of \$1,367 per contract when hospitals outsourced this activity to their GPOs. Taking into account the total cost of contracting for a base of 340 contracts, the researchers concluded it would cost a hospital \$353,147 to perform the functions performed by the GPOs; by using the GPOs, the hospital avoided \$154,927 in cost. To further substantiate their conclusions, the researchers cited evidence from a prior 1997

survey of UHC/VHA hospitals. The survey found that the higher the level of hospital participation in the GPO's contracts, the lower the total supply expense per adjusted discharge.

A 2009 follow-up study by ASU researchers pursued the same topic as the Novation study using a larger sample of 429 hospitals in 28 hospital systems.²⁹ The study reported that these hospitals routed 72.8% of their purchases in four product categories (commodities, pharmaceuticals, PPIs, and capital equipment) through their GPOs and achieved an estimated 18.7% in savings. The percentage of purchases routed through GPOs (and the savings achieved) varied by product category: general medical-surgical items = 82% (19% savings), inpatient pharmaceuticals = 89% (15% savings), and PPIs = 34-48% (15-17% savings). Respondents indicated that the absence of a GPO led to an increase in acquisition cost of 3.1% at the hospital level and 19.7% at the system level; absence of a GPO also led to an increase in workforce costs of 9 additional full-time-equivalents (FTEs) needed at the hospital level and 15 FTEs at the system level.

Muse & Associates conducted a parallel set of studies. In a 2000 report, Muse reported results from interviews conducted with purchasing and accounting managers in 221 hospitals across the country.³⁰ Respondents indicated that hospitals utilized GPOs for 72% of their non-labor purchases, and that GPOs helped them to achieve 10-15% savings on their supply purchases in 1999. Respondents also reported that GPO contracting (a) helped them to reduce provider staff time involved in product purchasing, (b) supplied them with product information they would otherwise have had to compile on their own, and (c) helped them to standardize product purchases. Utilizing the 72% statistic as a lower bound along with the 80% metric suggested by the GPO industry as an upper bound, Muse then computed the aggregate national savings in product purchases obtained by GPOs. They computed this by identifying national health expenditures (NHE) on hospitals and nursing homes using data from the Centers for Medicare and Medicaid Services (CMS), taking the proportion of those expenditures that are non-labor expenses (44.6% for hospitals, 25% for nursing homes), and then applying the percentage of non-

labor costs that GPOs mediate using the upper and lower bound statistics. They then applied the various savings rates in GPO contracts reported in the literature (10%, 15%, 18%) to derive the national savings due to GPOs.

In a 2002 report meant as a HIGPA/industry response to the first Senate hearing, Muse & Associates updated these findings utilizing more recent NHE data.³¹ The same benchmark statistics from the earlier report were applied to the updated NHE figures. The report emphasized the additional spending on products hospitals would bear if restrictions were placed on their utilization of GPOs (e.g., elimination of CAFs, reduction in GPO savings), and the impact on societal costs due to increased spending on Medicare, Medicaid, and Veterans Administration (VA) patients. In June 2005, Muse & Associates released a third report updating the findings from the prior two.³² HIGPA/HSCA commissioned Locus Systems in 2009 to update the findings through 2007 and 2008.^{33 34} Finally, in 2014, HSCA commissioned a consulting firm to update the 2009 report to estimate GPO savings for 2012 and projected savings over five and ten year periods.³⁵

The Lewin Group likewise conducted an analysis of the value provided by GPOs. In a 2003 report prepared for HIGPA, Lewin surveyed 79 purchasing managers representing 183 hospitals.³⁶ Similar to the studies above, they reported that hospitals purchased 75% of their supplies via GPO contracts. However, the larger the hospital, the smaller the percentage of supply purchases routed through GPOs: hospitals with less than 500 beds routed 80-83% of purchases through GPOs, while hospitals with 500+ beds routed only 63% of their purchases through GPOs. Moreover, the larger the hospital system, the smaller the percentage of purchases routed through the GPO: freestanding hospitals utilized GPOs for 79.6% of purchases, 3-hospital systems utilized GPOs for 70.2% of purchases, 6-hospital systems utilized GPOs for 58.3% of purchases, and 13-hospital systems utilized GPOs for only 50% of supply purchases. In other words, hospital reliance on GPOs diminished as hospitals grew larger in bed size, joined a hospital system, and developed larger systems. This reflected the ability of larger hospitals and systems to negotiate the same or better pricing as GPOs, as well as their ability to offer

vendors greater market penetration, higher levels of contract compliance, and greater product standardization in exchange for lower unit pricing.

Similar in vein to the ASU analysis, the Lewin Group report documented the variation in hospital compliance with GPO contracts across product areas. The percentage of hospitals with compliance levels of 60% or more was highest for commodity items (89.1%) and pharmaceuticals (84.9%), but much lower for PPIs (32.4%) and capital equipment (19.9%). Overall, hospitals reaped 17% savings in their utilization of GPO contracts across three product categories (medical-surgical, pharmaceuticals, and laboratory).

Furthermore, it has become more evident that hospitals do not see themselves as being held captive by their GPOs. Hospitals frequently belong to more than one GPO and, increasingly, have developed regional alliances to engage in collaborative purchasing. This lends credence to the idea that hospitals make their own decisions about how to engage the marketplace and see the GPO as only one of several channels (covered below).

Lynn Everard issued two rebuttals to the above claims regarding GPO value. In a 2003 white paper, Everard argued that historically, GPOs delivered value by obtaining price discounts for their members.³⁷ But such savings accrued more to smaller hospitals with low negotiating power and for mostly commodity items. Over time, with greater product commoditization (and thus, presumably, more competition among suppliers that would lower prices), the GPO value to hospitals has diminished. The value offered to suppliers - - in the form of easier market access, control over a large block of hospital purchases, and lower selling costs which allowed suppliers to keep their prices steady - - thus now exceeded the value to hospital members. He also opined that GPOs did not really act as agents of the hospital for several reasons:

- Low hospital compliance with GPO contracts
- Multiple hospital GPO memberships
- Hospital systems' use of GPO prices as benchmarks or leverage
- Lack of hospital input into GPO policy
- Inability of hospitals to evaluate or oversee GPO decision-making
- Historical hospital dependence on GPOs
- GPO fees paid by the suppliers

In a second white paper, Everard challenged the studies reviewed above regarding their findings on GPO cost savings.³⁸ He correctly observed there were no empirical studies substantiating the savings that GPOs help hospitals reap; the results were entirely based on opinion surveys. There was no definition of 'cost savings' and no clear demarcation of 'savings off of what'. He also argued that the CAFs charged by GPOs and distributed back to hospitals were not really savings, since vendors covered the cost of the CAFs through higher prices and limits on the discounts they offered.

Singer similarly criticized the studies reviewed above regarding the aggregate value provided by GPOs, contending they compared savings from GPOs with an unrealistic scenario of purchasing without GPOs present.³⁹ By contrast, Singer argued that GPOs did not pass along all of the CAFs they collected from suppliers (estimated to be 68-79% according to two 2005 OIG-DHHS reports - - see below). He suggested, as did those testifying in the Senate hearings, that GPOs suffered from agency problems in their relationships with hospitals by virtue of their receipt of CAFs from suppliers. He further suggested that removal of the safe harbor exemption for GPOs would not increase governmental spending on health care for the Medicare, Medicaid, and VA populations; instead, hospitals would capture a greater share of the CAFs now paid to the GPOs.

GPO Fees

A July 2003 GAO report focused on the business practices followed by GPOs in contracting for commodity items and medical devices. The report found that CAFs

generally conformed to the 3% safe harbor guideline (but not always); the modal fee was 2 percent, while the highest fees were typically achieved in contracts with private label manufacturers.⁴⁰ The report mentioned that having to pay these CAFs, along with the lower prices negotiated by the GPOs and their slow contracting processes, could pose a barrier for small suppliers.

In January 2005 and then again in May 2005, the Office of the Inspector General within the Department of Health and Human Services (OIG-DHHS) audited the history of CAFs collected by the GPOs.^{41 42} The January 2005 report examined two large GPOs from 1998-2002 and a third from 1999-2002. The CAFs collected amounted to \$1.8 billion, while GPO operating expenses amounted to \$487 million; this left the three GPOs with net revenues of \$1.313 billion. Of this surplus, \$898 million was distributed back to hospital members, while the residual \$415 million was kept by the GPOs as retained earnings. The GAO also investigated whether the hospitals that received these revenue distributions fully accounted for them on their Medicare cost reports. For the 21 hospitals examined, \$200 million of the \$255 million distributed by the GPOs was offset.

The May 2005 audit of three additional (and large) GPOs examined CAFs collected during the 2001-2003 period. Here the CAFs amounted to \$513 million, with \$238 million in operating expenses and \$275 million in net revenues. Of the \$275 million, \$217 million was distributed back to members and \$58 million was kept as retained earnings. Among the hospitals receiving these distributions, seven systems (comprising 38 hospitals) received 57% of the total (\$123 million out of \$217 million); \$115 million of this \$123 million amount was correctly offset on the hospitals' Medicare cost reports.

On a related note, the OIG-DHHS audited one of the large GPOs (Premier) to ascertain whether it was complying with the GPO safe harbor conditions by notifying and disclosing to its hospital members the CAFs it was receiving from suppliers.⁴³ Of the 107 hospitals belonging to Premier that responded to a survey, 70 received an advance agreement indicating that the GPO would receive a CAF from vendors based on the

hospital's volume of purchases, while 37 did not. Of these 37, 26 were subject to the safe harbor reporting requirements (they were affiliates of rather than owned by Premier's partners). Of the 107 respondents, 72 received a report showing actual supplier payments to Premier, while 35 did not; of the latter, only 8 were subject to the safe harbor reporting requirements. According to the OIG, part of the problem reflected Premier's reliance on its partners and group affiliates to disseminate information to its hospital members.

Finally, a 2010 GAO report stated that the average CAFs paid by suppliers to GPOs in 2008 ranged from 1.22% to 2.25% of purchases, weighted by purchasing volume.⁴⁴ The lower level of fees received, compared to earlier levels reported above, reflected the new codes of conduct: four GPOs reported they no longer received CAFs in excess of three percent. Suppliers similarly reported to the GAO that they were paying lower CAFs to the GPOs.

GPO Contracting Practices

The July 2003 GAO report stated that seven GPOs used sole-source contracts to achieve lower product prices.⁴⁵ Five of the seven GPOs queried used sole-source contracts for anywhere from 2-46% of their medical surgical supply dollar volume; the two largest GPOs used sole-source contracts for 19% and 42% of this dollar volume, respectively. Use of sole-source contracts varied by commodity item versus PPIs for smaller and larger GPOs: among smaller GPOs, commodity items represented 62-91% of the dollar volume purchased using such contracts, whereas in one of the two largest GPOs, PPIs represented 82% of the dollar volume purchased through such contracts.

The 2003 GAO report also identified three types of bundled contracts used by the GPOs: bundles of complementary products from one supplier, bundles of unrelated products from the same supplier, and bundles of products from multiple suppliers whereby hospitals were required to purchase a minimum percentage across product categories to receive discounted pricing. Six of the seven large GPOs used some form of bundling. According to the GAO, four GPOs used the first type of bundled contract; such bundles

were included in a small percentage of the GPO's contracts. Three GPOs used the second type of bundled contract; one of the two large GPOs used the second type of bundled contract for 40% of its medical-surgical supply dollar volume. Four GPOs used the third type of bundled contract; one large GPO used this type of bundled contract for 20% of its volume.

The GAO report also noted that GPO use of bundling was possibly declining. Data supplied by one GPO showed a decline in one type of bundled contract between 2001 and 2003. This trend was consistent with comments made by one manufacturer and two medical-surgical product distributors, who reported that GPOs were "less interested in bundling different manufacturers together," "GPOs have fewer bundling arrangements," and "some bundles were pulled apart."

Moreover, in 2002 (the year of the first Senate hearing), nearly one-third of contracts were signed with new suppliers who did not previously hold GPO contracts. Across the seven GPOs studied, 16-55% of all contracts were with new, non-incumbent suppliers. This represented evidence of a leveling in the contracting process and greater access to GPO contracts by new suppliers. The most important parties consulted and making decisions on which vendor to contract with were customers (e.g., clinicians) who requested those suppliers' products.

Finally, the July 2003 GAO report noted that the two largest GPOs typically awarded five-year contracts, while the other five typically used three-year awards. The GAO also found the GPOs had taken steps to address concerns about their contracting practices, but it was too early to evaluate their efforts. The GAO noted there were variations in GPO efforts to address business practices (e.g., variations in their codes of conduct and the practices specified in those codes).

It is worth noting that some of the disputed practices discussed above - - such as group purchasing, product bundles, sole-source contracts, and committed purchasing contracts -

- are widely used in other industries. A report issued by the Center for Advanced Purchasing Studies at Arizona State University documented that purchasing consortiums like GPOs constitute a long-standing form of buying behavior that helps buyers to achieve cost savings of 13.4%.⁴⁶ A Rand Corporation report noted the increased interest in the bundling of services supplied to the U.S. Department of Defense and the improvements in supplier performance and product cost associated with bundling.⁴⁷

GPO Customer Service

Another review by the GAO found that GPOs render a range of services to their hospital members.⁴⁸ The six largest GPOs offered custom contracting, clinical evaluation and product standardization, and new technology assessment. Five of the six GPOs also offered e-commerce and benchmarking data services. Funding for these services was provided by the CAFs collected by the GPOs or through charges to the hospitals themselves.

GPO Clinical Review Processes

In addition to how GPOs contract with suppliers, research has also examined how GPOs clinically review the products they purchase for hospitals that are used in patient care. On behalf of HIGPA, the Lewin Group surveyed five hospital systems and six GPOs during 2002 to ascertain how products considered for contracting were clinically reviewed.⁴⁹ Lewin reported that hospital systems and GPOs utilized committees of clinical experts and administrators to review products, drew upon independent technology assessments (e.g., ECRI) and literature reviews (e.g., MEDLINE), monitored breakthrough technologies and employed mechanisms to incorporate them into the process of product review, and had ongoing reviews of technologies and sometimes perpetual review of new technologies. They also reported that GPOs helped to facilitate clinical trials of new products by their member hospitals. Product review mechanisms included value analysis committees and product evaluation committees (for medical-surgical devices), pharmacy and therapeutics committees (for drugs), and capital committees (for capital equipment).

A subsequent review by the GAO confirmed that the six largest GPOs they studied offer clinical evaluation of products and assessments of new technology.⁵⁰ Clinical evaluation was conducted through clinical advisory committees comprised of clinicians from member hospitals. Reviews of innovative technologies were also bolstered by GPO codes of conduct and newly instituted mechanisms to support the inclusion of innovative products on GPO contracts.

GPO Oversight, Codes of Conduct, and Self-Regulation

The oversight of GPO activities was an ongoing issue of contention during the Senate hearings. The Senate followed up on this issue several times through GAO investigations. In 2003, the GAO reported that selected GPOs had adopted codes of conduct or revised their existing codes to respond to criticisms about their business practices.⁵¹ Due to the recent nature of the codes, the GAO could not evaluate their impact; however, it did state that two suppliers and two distributors had noticed improvements in contracting practices, and that one supplier had received several GPO contracts compared to none previously. The GAO also noted variations across the GPOs in their conduct codes addressing specific issues such as: caps on CAFs, limits on use of sole-source contracts for PPIs, and restrictions on using bundles for unrelated products and for PPIs.

The Senate subsequently asked the GAO to review the various oversight activities aimed at GPOs conducted by DHHS, the Department of Justice, and the Federal Trade Commission since 2004, as well as the GPO's own self-regulatory approach exercised through the HGPII effort.⁵² The report noted that GPOs were subject to various laws that the three federal agencies were supposed to enforce, but the agencies did not routinely exercise this authority. The OIG-DHHS reported it had not imposed any administrative penalties on GPOs since 2004, while the FTC reported it had not undertaken any enforcement actions against GPOs since 2004. For its part, the HGPII has continued to monitor the business practices of its GPO members and added some new activities (an ethics advisory council for best practices) between 2010 and 2012.

Shortly thereafter, two former OIG-DHHS officials submitted a white paper to the Healthcare Supply Chain Association (HSCA) on the history of OIG oversight regarding the GPOs.⁵³ Their report summarized the OIG-DHHS' historical stance that the CAFs collected by the GPOs from suppliers should be permitted and that the safe harbor for GPOs remained viable. They concluded that, "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."

An additional GAO report stated that the GPOs' codes of conduct had varied impacts across GPOs, hospitals, and suppliers. The GPOs informed the GAO their codes had altered their contracting processes (limits on use of sole-source contracts, greater use of multi-source contracts, limits on use of product bundles), selection of innovative products, CAFs, potential conflicts of interest, and the transparency and accountability of their business practices. Some hospitals and suppliers noted there were more vendors available to contract with via multi-source contracts, although this resulted in higher product prices. To obtain lower pricing, the hospitals resorted to direct contracts with the supplier and used the GPO price as their starting point in price negotiations. Some hospitals also resorted on their own to employ prior GPO-hosted practices of sole-source contracts, product bundles, and committed purchasing contracts. Some hospitals and suppliers echoed the improvement in transparency, while others did not offer any comments regarding the impact of the codes on the addition of innovative products to GPO contracts.⁵⁴

HGPII has released an annual report to the public on its members' adherence to its six principles and their efforts to promulgate and enforce a code of ethical conduct.⁵⁵ The HGPII initiative has since expanded from nine to eleven large GPOs, and in recent years has added a random site visit by an independent coordinator to review the GPO's policies regarding supplier agreements, vendor forums, and CAFs.

In 2014, Rahman, Schneller, and Wilson reviewed the role of codes of conduct for advancing corporate social responsibility as well as the evolution of the HIGPA code.⁵⁶ When confronted by negative findings or allegations concerning the behavior of its members, an industry sector often develops mechanisms to both improve its image and buffer itself against both criticism and intervention (formal regulation).⁵⁷ Codes of conduct have served as a key mechanism to achieve this goal. The 1987 American Society of Association Executives survey revealed that 43% of industry associations had promulgated a code of conduct; 78% of top 1,000 organizations had drawn up such a code.⁵⁸ Most attempts at industry self-regulation have involved national trade associations as well as professional associations (representing processors, manufacturers, and service industries) in a joint effort to advance the business practices of their industry members.⁵⁹

Rahman et al. then analyzed the HIGPA code of conduct and its embrace by GPOs and their hospital members. They concluded the annual reporting mechanism and questionnaire established “a footing for government and the GPO industry itself to assess GPOs.” They also concluded that the Code responded to “concerns regarding administrative fees, market maintenance, product positioning and the behavior of individuals working within GPOs,” and served as a “demonstration of citizenship” and “purchasing social responsibility”.⁶⁰

Competitive Market for National GPOs

One issue permeating the GPO literature is whether or not the GPO marketplace is competitive. This issue is important because rivalry can spur GPO efforts to achieve lower pricing and greater customer service for their hospital members. In an early statement on this issue sponsored by HIGPA, Hovenkamp argued that the GPO market was competitive by virtue of several facts: (1) the national GPOs faced competition from regional GPOs and hospital systems that handled their own contracting (see next section), (2) no one GPO controlled more than 10-15% of the market, (3) hospitals belonged to

multiple GPOs and thus had divided loyalties to any one GPO, and (4) there were no entry barriers to the GPO market (as evidenced by the entrance of MedAssets in the late 1990s). Hovenkamp also inferred that the GPO sector met both conditions in the FTC/DOJ antitrust safety zone for GPOs⁶¹: the purchases of any one GPO were less than 35% of total sales of the purchased product/service in the relevant market, and the cost of products/services purchased jointly was less than 20% of the total revenues from all products/services sold by each competing supplier in the joint purchasing arrangement.⁶²

As further substantiation for this argument, two academic researchers examined the Herfindahl-Hirschman Index (HHI) - - a standard measure of competitiveness - - for the GPO market.⁶³ Hovenkamp computed an HHI for the GPO marketplace of 410-450, clearly in the range of high competition. In testimony presented to the Federal Trade Commission, Burns noted that the large share of total GPO volume accounted for by the top GPOs provided a misleading view of how concentrated the industry in fact was, especially given that hospitals often bought products directly from suppliers, as well as the fact that GPO-mediated purchases averaged only 72% across hospitals and varied greatly across product categories.⁶⁴ This point refuted claims by another researcher that the GPO marketplace was highly concentrated and oligopolistic in nature because a handful of GPOs controlled over 80% of the supplies purchased through such buying groups.⁶⁵ This researcher's other claim that similarities among GPOs left them no incentive to compete with one another was similarly wrong. The fact that GPOs (a) offered the same services, (b) vied for the same supplier and hospital customers, and (c) vied with equally large GPOs, directly confirmed Michael Porter's conditions for competitive rivalry.⁶⁶

Additional studies by academic researchers considered the possible concerns over GPO monopsony power and concluded that GPOs exerted pro-competitive effects.^{67 68 69 70 71 72 73 74} In general, researchers found that GPOs help providers to lower their total purchasing costs, and that CAFs exert little impact on these costs. Moreover, many of the questioned practices employed by GPOs (e.g., volume-based discounts, sole-source

contracts) may serve to reduce input prices for hospital members. One study argued that GPO contracts not only helped to reduce supply prices, but also that the loss of GPO contracts prompted suppliers to counter-detail these contracts, maintain a presence in the hospital accounts, and thereby further increase pricing pressures.⁷⁵ One of the studies did suggest that GPOs dampened the innovation incentives of suppliers, however. Another study echoed allegations raised in the Senate hearings that GPOs limited market entry by new suppliers and engaged in exclusive (and thus exclusionary) contracts.⁷⁶ It should be noted that all of these studies were typically based on modeling exercises and theoretical arguments rather than empirical analyses.

Articles and white papers by several attorneys attacked GPOs and their contracting practices based on their alleged anticompetitive effects.^{77 78 79} These papers typically argued that GPO contracts with large and diversified suppliers foreclose the market for small niche (and innovative) suppliers. Such foreclosure operates through the use of the contracting practices analyzed above: sole-source contracts, market share discounts, product bundles, and CAFs (labeled “kickbacks” by GPO critics). By contrast, articles and white papers by other attorneys supported the pro-competitive view of GPOs: i.e., GPOs promote rivalry among suppliers and lower input prices for buyers.^{80 81 82} They cautioned, however, that antitrust agencies ensure that the two FTC/DOJ guidelines for GPO safety zones be strictly monitored and enforced. Most of these papers and reports were supported by either the opponents of GPOs or the GPO trade association HIGPA/HSCA, and thus were often written by individuals who served as expert witnesses in antitrust cases brought by small suppliers who felt they were foreclosed by GPO contracts.

Growing Competition from Regional GPOs

More recently, a number of hospital systems have developed what Rahman and colleagues describe as “captive GPOs” to serve their own members and increasingly like-minded hospitals and systems within their region.⁸³ These are variously known today as regional aggregation groups, regional purchasing coalitions, regional purchasing

alliances, and custom supply chain networks. The regional GPOs pool the purchasing of non-related hospitals, hospital systems, and integrated delivery networks (IDNs) that typically share a common locality, and may even belong to the same national GPO. The members work together to optimize their GPO portfolio contracts, in the belief that “everyone believes they can do better” regarding product pricing. They appear to focus less on developing tighter cost controls (e.g., through better management of product utilization) and more on obtaining supplemental savings from additional contracts. They offer hospitals yet another vehicle to get providers to work together on purchasing. This may lead to more intimate efforts to work on contract commitment which may help hospitals get to a higher tier of committed purchasing than they could do on their own or with their national GPOs. The theory is that it is easier to get agreement among a smaller number of hospitals to commit a high percentage (e.g., 85%) of purchases through the regional GPOs. This is one reason why the national GPOs could not consistently obtain the lowest prices.

The existence of the regional GPOs serves as recognition that national GPOs cannot perform the following functions well:

- Provide hands-on service to smaller and rural hospitals
- Offer a face-to-face relationship with the hospital customer/member
- Influence hospital members’ use of negotiated contracts
- Address idiosyncratic needs of members
- Negotiate local contracts for members with local vendors of supplies and services
- Contract for supplies such as medical gas, perishable food, medical waste removal, and equipment maintenance - - which are more local than national
- Offer scale economies to local vendors
- Assist local hospitals with shared services (order processing, distribution, warehousing, invoice processing)
- Assist hospitals with a shared information technology platform to help them with these shared services, and thus enable them to act as a single organization (even though virtual)

The regional GPOs thus constitute an effort to combine and balance the scale of large purchasing groups with the nimbleness of small hospital networks. They are also rooted in the belief that smaller groups have greater alignment and goals when it comes to purchasing and committed contracting. Finally, they exist to complement national GPOs and add local savings to national savings. As such, national GPOs may actually partner with and support them; in such cases, the regional GPOs may be affiliates of the national GPOs but are not required to use national GPOs. This creates another layer of purchasing with suppliers and, of importance, utilizing national GPO contracts as ceilings from which to begin negotiations. It remains to be seen if the hospital trend to insource key supply chain functions (e.g., contracting, strategic sourcing, logistics) will result in what has been described as fully integrated supply chain companies (FISCOs), competing directly with national GPOs and distributors.⁸⁴

In addition to the regional GPOs, there has also been a recent rise in “virtual GPOs” using alliance models. Examples include Ascension Health Alliance, CHA Shared Services Program, BJC Collaborative, MNS Supply Chain Network, Dignity Health Purchasing Network, and Shared Clarity. These models look quite similar to the local and regional purchasing groups started by state hospital associations in the 1960s, suggesting a “back to the roots” movement in group purchasing.

At this time, there is no systematic study of the consequences of the proliferation of local, regional, and virtual group purchasing alliances - - including those that are independent of national GPOs or those supported by national GPO contracts and augmented by local contracts. There is also no systematic research on the proliferation of e-commerce platforms for purchasing or the consequences of hospital access to pricing by independent price analytic services (e.g., Broadjump). Such developments suggest that the marketplace in which GPOs currently operate is becoming increasingly competitive.

GPOs' Alleged Exclusionary Agreements and Anti-Competitive Practices

A major bone of contention in the GPO debate has been the alleged presence of anti-competitive GPO practices and supplier-GPO agreements that serve to exclude smaller and potentially more innovative manufacturers from the marketplace. A leading proponent of this view was Professor Einar Elhauge (referenced above). Given the prominence of his writings in the GPO literature, Senate hearings, and GPO litigation, it is worthwhile to review his opinions in some detail.

Elhauge advanced several arguments regarding GPO activities. First, GPOs engaged in anti-competitive strategies with large incumbent manufacturers to establish and maintain their monopoly power in supplier markets. Second, these suppliers used their GPO contracting partners to erect entry barriers that inhibit new innovative suppliers from entering the market. Third, suppliers induced GPOs to enter these anti-competitive contracts by paying CAFs to the GPOs, which amounted to hijacking them. Fourth, GPOs acted in the suppliers' interests, forcing their hospital members to buy products they may not prefer and imposing contracts on them that governed and regimented their purchases. Fifth, the low market shares held by smaller and innovative suppliers reflected these anti-competitive agreements, which were designed to foreclose the product market and generated the "low headroom" hospitals had available to them to buy from alternate suppliers. Sixth, the specific tactics used by the suppliers to effect foreclosure included bundled contracts, sole-source and dual-source contracts, and share-based discounts (lower prices for higher committed levels of products purchased). Seventh, incumbent suppliers exercised their market power to obtain these contracts and then pressured GPOs and hospitals to conform to them by threatening higher prices if they did not.

According to Elhauge, these practices had the effect of restraining sales by smaller suppliers, denying them the opportunity to increase their production levels to achieve scale economies and efficiencies (at which point they could sell their products more cheaply and be more competitive), limiting their expansion, and thus foreclosing the product market. As a consequence, hospital customers faced a product market with higher

product prices and lower product quality (due to the absence of the smaller and presumably more innovative suppliers). Hospitals were thus unwitting stooges in the contracts between incumbent suppliers and the GPOs.

Other professors from law and business schools seriously challenged Elhauge's arguments regarding the anti-competitive effects of product bundling and quantity-linked discounts.^{85 86} Some of their points rested on the widely acknowledged tradeoff that buyers have to make between access/choice and cost. Thus, if buyers commit to purchasing higher volumes of a single specific product from one supplier, they can obtain that product at a lower cost; if buyers want to exercise choice among alternate suppliers of rival products, they can purchase smaller amounts of each at a higher price. This happens because buyers promise higher volumes to the supplier, which can then plan its manufacturing runs accordingly, achieve production economies, and pass along some of the efficiencies to buyers in the form of lower prices.

Some of their arguments also rested on the widespread use of bundled discounts and committed purchasing contracts in other industries - - which have the effect of lowering prices and increasing competition among suppliers to win these contracts. Additional arguments reflected the role that large intermediaries (like GPOs, pharmacy benefit managers or PBMs, health insurers) play in health care to reduce pricing opportunism by suppliers and counteract the power of suppliers. This is in essence what Senator Schumer argued in the 2006 Senate hearings. Finally, these observers noted that the presence of sole-source contracts did not inhibit hospital buyers from using alternative suppliers not on contract. The presence of sole-source contracts also did not reduce the survival prospects of smaller or larger competitors who could still successfully (a) compete for GPO contracts in the next round of bid contracting, or (b) compete for individual hospital contracts in the interim via counter-detailing the GPO contract.

In a follow-up report prepared for HIGPA, Hovenkamp took issue with Elhauge's assertion that GPO contracts with large suppliers had the intent and impact of excluding

smaller and innovative suppliers from the marketplace.⁸⁷ Hovenkamp argued that suppliers, GPOs, and hospitals were all independent of one another with little vertical integration to assure suppliers of dedicated purchases by hospital members.⁸⁸ Not only did each GPO have low market share, but hospitals could and did join different GPOs over time and switched their purchases from one GPO to another. Even in the presence of a sole-source contract, only 20% of the market was potentially closed to a small supplier, leaving 80% of the remaining market to pursue for product sales. The largest GPO might account for no more than 15% of the market share for a given device, leaving an unconcentrated market for suppliers to contest for. In sum, GPOs were neither monopolists nor monopsonists (controlling markets upstream or downstream).

Access to Innovative Technology

Three bits of evidence question the claims that GPOs impeded market entry by innovative suppliers and hospital access by their sales representatives. First, an analysis of the entry and exit rates of new startups in the medical device sector revealed no slowdown in market entry by entrepreneurial startups during the period that spanned the 1990s and early 2000s - - the same period when GPOs grew.⁸⁹ Major drivers of market entry by new device firms included the number of entries in prior years, prior merger and acquisition activity in the firm's sector, the number and valuation of prior initial public offerings for firms in that sector, the amount of venture capital funding invested in firms in that sector, and venture capitalists' views of rival investments in biotechnology.

Second, surveys of hospital vice-presidents for materials management disagreed with the contention that their GPOs had blocked their access to innovative devices and the manufacturers that made them.⁹⁰ Conversely, when asked if their primary national GPO brought innovative products to their attention, materials managers gave their GPO a score of 3.65 (using a Likert scale ranging from 1 – 5, where 5 expressed the highest level of satisfaction). They gave slightly lower ratings (score of 3.24) of their GPO's ability to increase their knowledge of innovative devices and manufacturers.

Third, GPOs such as Premier have hosted annual meetings where medical products innovators can network and share their innovations with clinicians from the GPO member hospitals. Such meetings not only help innovative firms get their products in front of clinicians but also provide feedback from clinical customers for product iterations. Premier also hosts a program called “SEEDS” (Sourcing Education and Enrichment for Diverse and Small Suppliers) that provides mentoring and coaching to smaller manufacturers to help them scale their businesses.⁹¹

Small Supplier Litigation Claims

Finally, starting in the mid-1990s and extending into the early-mid 2000s, several small device manufacturers sought judgments in U.S. District Court against the GPOs and the larger suppliers with which they contracted. The small manufacturers included Kinetic Concepts (maker of specialty beds), Retractable Technologies Inc. (maker of safety needles), Masimo Corporation (maker of pulse oximeters), Applied Medical Corporation and ConMed Corporation (makers of trocars and clip applicators), and Rochester Medical (maker of specialty catheters). Several of their executives testified in the Senate hearings. The earlier cases (KCI, RTI, Masimo) settled in favor of the plaintiff; the three latter cases were either dismissed or settled with only small payments made by the defendant. More tellingly, these cases appear to have subsided over time.

A major issue in nearly all of these cases was the anti-competitive nature of bundled, sole-source contracts.⁹² Plaintiffs typically alleged that such contracts unfairly excluded them and restricted hospital access to their technology. Defendants countered (successfully in the latter cases) that the small manufacturers had ample opportunity to sell their products, that the contracts in question allowed for considerable ‘headroom’ for hospital purchasing of new technology, that the GPOs did not mandate what products clinicians had to buy, and that the technology of the small manufacturers may not have been as claimed. In support of this last assertion, sales figures for the small manufacturers barely rose when they were finally added to GPO contracts. This suggested that GPOs were not that adept in moving market share for those vendors it

contracted with and, conversely, they did not pose a sales barrier to those vendors they did not contract with. This also suggested that the products made by the small manufacturers might not have been desired by clinicians: even when offered on GPO contracts, clinicians still did not buy them.

Some interesting research conducted on the comparative effectiveness of devices made by rival device manufacturers at this time provided partial substantiation for this conclusion. In one research study, 45 surgeons went into animal labs at six academic medical centers around the country and operated on pigs using the products made by all eight suppliers of trocars and clip applicators - - products at the center of some of the litigation discussed above.⁹³ The surgeons utilized different vendors' products in different product categories as they operated, commenting to reviewers on the functionality and performance of each device. The analysis showed that the supplier receiving the top performance rating in most product categories was the supplier with the largest market share; this finding held even after controlling for the surgeon's prior training and vendor preference. Moreover, the analysis showed that the two vendors who had brought suit against the leading supplier were rated lower (often significantly lower) than the market leader.

Continued Hospital Use of and Satisfaction with GPO Services

Hospitals are clearly the major customer of the GPOs. The historical record is quite clear that hospitals and their state hospital associations were instrumental in forming the GPOs in the 1960s, and are once again active in establishing virtual GPOs. According to the late management sage, Peter Drucker, the best way to assess a firm's performance is to ask its customers how satisfied they are with the company. Hospitals have demonstrated their satisfaction with their GPOs in at least four important ways. First, studies conducted over time show that the vast majority of hospitals (90-98%) still have GPO memberships. Second, studies show that hospitals still belong to only a small number of GPOs (1.6 – 2.6 GPO memberships). Third, studies over time show that hospitals still route the majority (66-72%) of their supply purchases through GPOs. Fourth, studies over time

have repeatedly reported high hospital satisfaction levels with their GPOs, particularly with GPO pricing and cost savings.^{94 95 96 97 98} In the eyes of Professor Elhauge, hospitals may be the unwitting dupes of GPOs; alternatively, in the eyes of Professor Drucker, hospitals may simply be satisfied customers.

In perhaps the first national survey of hospital materials managers in 2005, Neil found that 49% of hospitals and 65% of hospital systems were ‘very satisfied’ with their primary GPO relationship; another 42% of hospitals and 24% of hospital systems were ‘satisfied’. The percent of hospitals and systems stating they were dissatisfied was only 9% and 12%, respectively.⁹⁹

This is not to say that hospitals are satisfied with everything about their GPOs. In another national survey, hospital vice-presidents for materials management assigned their national GPO highest ratings (5=very satisfied, 1=very dissatisfied) for ‘low pricing’ (3.92 out of 5.00), contracting convenience (3.92), and ‘multi-source contracts’ (3.91).¹⁰⁰ GPOs received more modest ratings on ‘supply chain analysis and improvement’ (3.51), ‘hospital input and voice in decision-making’ (3.50), ‘benchmarking, product selection, and product conversion’ (3.49), and ‘clinical improvements’ (3.48). GPO services receiving lower (but still positive) assessments included ‘pricing information tools’ (3.32), ‘outsourcing’ (3.31), and ‘education’ (3.26). The only GPO service receiving a negative assessment was ‘information system tools’ (2.89), although the GPO’s provision of a web-based contract catalog was very highly rated (4.06). Despite these variations, the research found that managers were quite satisfied with their GPO overall (4.06). Managers’ satisfaction with their GPO was significantly and positively correlated with utilization of the GPO (i.e., the level of hospital spending routed through the GPO), but not strongly so.

Schneller’s 2009 survey similarly revealed that hospitals have a high overall level of satisfaction (5=highly satisfied, 1=highly dissatisfied) with their GPO (4.1 out of 5.0), which was again correlated with greater utilization of the GPO’s contracts. However,

hospitals and systems have relatively high levels of expectations for GPO performance that are not always met. The variability in met expectations is higher for GPO pricing than for GPO contracting. Expectations are met more for ‘lowest pricing’ on pharmacy products (3.9 out of 5.0), commodity items (3.9), and medical-surgical products (3.8), but not for physician preference items (2.7). Expectations are also largely met for ‘financial returns’ via disbursed CAFs (3.7) and ‘managing supplier items and conditions’ (3.6), and somewhat for ‘high guaranteed savings’ (3.4). When pricing expectations are not met, hospitals and systems are likely to engage in self-contracting.¹⁰¹ The degree to which hospital expectations regarding GPO contracting are met exhibit a narrow range of variation: ‘breadth of portfolio’ (3.9), ‘contract flexibility’ (3.7), ‘contract management support’ (3.6), and ‘identify new products’ (3.5).

In 2010, the industry conducted a national survey of hospitals’ use of and satisfaction with their GPOs.¹⁰² GPOs received ‘very satisfied’ ratings from 30% of respondents and ‘satisfied’ ratings from another 60%. On specific items, hospitals expressed fairly uniform levels of satisfaction: ‘pricing/savings’ (36% very satisfied, 53% satisfied), ‘clinical/consulting’ (24% very satisfied, 54% satisfied), and ‘customer service/responsiveness’ (37% very satisfied, 51% satisfied).

While hospitals are not satisfied with every service provided by their GPOs, they are more or less equally satisfied with their national GPOs. In a national survey conducted in 2005-06, hospital vice-presidents for materials management rated the national GPOs on a variety of performance dimensions. Satisfaction levels across the seven major GPOs were quite similar. Cooperatively-based GPOs tended to receive slightly lower evaluations than those not organized as cooperatives; the magnitude of the differences was small and often statistically insignificant, however.¹⁰³ The data suggested that the national GPOs were not strongly differentiated from one another, at least in terms of their member evaluations. Such findings are important for two reasons. First, the GPOs have striven to gain competitive advantage over another by developing distinctive capabilities and differentiating their offerings; such efforts had not yet paid off by 2005-06.¹⁰⁴ ¹⁰⁵ Second,

such lack of differentiation is likely associated with rivalry among the GPOs and thus competitive market conditions.

GPOs and Drug Shortages

Recently, long-time critics of the GPO industry have blamed the GPOs for the shortages of prescription drugs experienced by hospitals and physician offices between 2005 and 2012.¹⁰⁶ GPOs allegedly propelled the shortage by squeezing supplier margins, awarding sole-source contracts, and pursuing other strategies that reduced the number of vendors available to supply the needed products. The majority of the drugs in short supply were sterile injectables (74% of the drug shortage in 2010), particularly for oncology. Some analysts discussed the possibility of linkages between these drug shortages and GPO sales practices. The argument here was that the heavy use (60%) of sole-source contracts for sterile injectable molecules and the resulting tendency for a small number of suppliers to have these contracts contributed to a concentrated supplier market that left few alternative sources of supply and lower market access to new entrants - - all of which might exacerbate shortages.¹⁰⁷

By contrast, the literature on the drug shortages experienced in recent years points to many other causes beyond GPOs. These include: manufacturing difficulties, shortages of raw materials, imbalances in supply and demand, FDA oversight and enforcement actions, the impact on generic drug pricing by the Medicare Modernization Act, activities in the secondary drug distribution marketplace, and other unknown reasons.^{108 109 110} The Healthcare Supply Chain Association (HSCA) commissioned two reports on the causes of the shortages and the roles played by GPOs to alleviate them.^{111 112}

Group Purchasing in International Contexts

There is a growing literature on “collaborative procurement” and public procurement (with a focus on healthcare) outside the US.^{113 114 115 116} This literature emphasizes the benefits (e.g., scale economies, buying power, pooling of expertise) of collaborative procurement for both suppliers and contracting authorities. At the same time, the

fragmentation among purchasing bodies (national government vs. local government vs. organizational) allows for contractual autonomy and individual procurement.¹¹⁷ Several studies compare health care procurement in the U.S. and UK.¹¹⁸ The UK's National Health Service (NHS) established the Purchasing and Supply Agency to coordinate contracting at the national level; the latter, however, encouraged the formation of regional cooperatives to foster local level initiatives in supply purchasing.

As suggested by the titles of these references, much of the attention focuses on purchasing in the public sector and, within the EU, on the role of both the EU and sovereign governments in purchasing. Group purchasing is clearly an international phenomenon that is often conducted by the public sector. By contrast, healthcare group purchasing in the U.S. tends to take place within the context of private sector organizations (both not-for-profit and investor owned systems) as well as public health care delivery systems (including some public academic health centers) participating in GPO purchasing arrangements as permitted by state procurement statutes.

Summary of the Evidence on GPO Performance: What Have We Learned?

Beginning in 2002 with the *New York Times* exposé and the Senate hearing, GPOs have been accused of conducting many negative business practices and exerting anti-competitive effects in supplier markets. Over the next few years, a host of reports were issued in support of and in response to these allegations. Many of these reports were underwritten or otherwise sponsored by opponents and proponents of the GPOs. These included the trade associations for small suppliers and the GPOs. Some reports were produced as part of the testimony presented in the Senate hearings; others were prepared as expert witness reports to be used in litigation involving the GPOs and the large suppliers with which they contracted.

Following these early articles, reports, and testimony, there has been a small but growing volume of academic analyses of GPOs and group purchasing. Most of their analyses are based on economic theory and models; a few include survey data on GPO performance.

A handful of academic texts have also analyzed the GPOs in terms of their business models, business practices, and strategies in working with suppliers and hospitals.

The sections above attempt to outline the allegations and issues concerning GPO performance, and then review the evidence base that exists to address them. Overall, the preponderance of the evidence, such as it is, does not support the anti-GPO allegations. Most of these allegations rest on anecdotal evidence (e.g., reports in the *New York Times*), case evidence that has surfaced in litigation, and small-scale surveys of GPO pricing and practices (e.g., by the GAO). These allegations and (to the extent it exists) any supporting evidence stem mainly from the early 2000s. Indeed, many of the stories in the *New York Times* critical of the GPOs date from 2002 (see footnote 14 above).

To be sure, most of the evidence refuting these allegations similarly rests on small-scale studies and a handful of large-scale survey research studies. However, the evidence base from the survey research findings and academic analyses has been growing steadily and is more recent in origin. The findings are consistent with the two academic texts that appeared earlier. Together, they suggest (more or less consistently) that GPOs serve the interests of their hospital customers in ways these customers value. There are no empirical studies that even hint that hospitals are dissatisfied with their GPOs, and several studies that document how well their needs are met by GPOs. A report issued by the former head of the DHHS-OIG further suggests that the GPOs serve societal interests by helping hospitals to lower their purchasing costs, and thus warrant continued protection by the safe harbor and exemption from the anti-kickback statute.

The disjunction between the early allegations and negative press and the later, more positive evidence may partly reflect the GPO industry's efforts to change. Undoubtedly, the voluntary effort was prompted by the negative press and Senate hearings, and constituted an attempt at self-policing that would avoid external regulation. Moreover, academics have acknowledged that such voluntary efforts are imperfect, difficult to evaluate and enforce, and continually subject to skepticism. Nevertheless, the voluntary

industry effort met with some positive though preliminary assessment by the GAO (in its 2003 and 2010 reports), which noted changes in GPO contracting practices. The GAO reports also mentioned the positive assessments made by the GPOs' stakeholders interviewed. The HIGPII Code of Conduct has continued to operate without controversy; federal watchdog agencies have not undertaken any enforcement actions; defendants prevailed in many of the later litigation cases brought against the large suppliers and their GPO contracting practices; and the incidence of such cases appears to have subsided. The trail of behavior documented by the Code of Conduct may well demonstrate GPO citizenship and purchasing social responsibility.

It is worth noting that the Code of Conduct constituted a response to a Senate inquiry that in many ways was stirred by criticisms from small suppliers who felt excluded from the GPO marketplace. The Code was not prompted by criticisms from the GPOs' customers (i.e., hospitals and health care systems).

Finally, much of the criticism of GPOs has come without attention to the changing landscape of health care purchasing. The purchasing environment has become much more competitive. In recent years, suppliers have witnessed a noticeable diversification in the array of local, regional, and virtual GPOs - - as well as self-contracting by hospitals. These alternative sources of contracting both complement and compete with national GPO contracts which suppliers once decried and which have been the only subject of inquiry. Simply having a contract with a national GPO does not guarantee sales to GPO-contracted suppliers. Regional and other alliances also enter into local contracts for their hospital customers. Thus, off-contract suppliers that lack a national GPO point of access nevertheless have multiple avenues to secure business on the basis of pricing or clinically differentiated products. If anything, the evidence suggests that GPOs are pro-competitive rather than anti-competitive, and thus serve societal interests as well as hospital interests.

Likewise, much of the GPO criticism has come without attention to the changes in hospital finance. Hospitals have faced a string of reimbursement cuts under Federal

payment programs such as Medicare and Medicaid. These include payment-to-cost (PCR) ratios of 92% and 93% for these two programs in 2010, respectively.¹¹⁹ They also include cuts from the Sequestration, cuts in Medicaid disproportionate share hospital payments, the 3-day window cut, the two-midnight offset, and MS-DRG coding offsets. Beginning Oct. 1, 2013, CMS began to reduce payments to 2,225 hospitals in 49 states (except Maryland) as part of the Hospital Readmissions Reductions Program.

In addition to these cuts, hospitals have yet to generate efficiencies and savings from the formation of multi-hospital systems and vertical integration efforts with physicians.^{120 121} As a result, hospitals have few (if any) avenues left to generate savings to deal with reduced reimbursement. Group purchasing and, more generally, improvements in hospital supply chain management represent perhaps their best hope for the future.

This is especially critical given that supplies and logistics account for up to 30 percent of a hospital's cost structure, second only to labor.¹²² This is also important because responsibility for procurement and supply management is dispersed across multiple departments inside the hospital. The supply chain thus remains perhaps as the last area of hospital operations without comprehensive and professional management. There is growing recognition of the importance of supply chain management for increasing the efficiency of the health care system, but very little evidence for its effects.^{123 124 125 126}

Appendix I

Senate Hearings Overview

Senate Hearings April 2002

In April 2002, the month following the initial *New York Times* article, the Senate Judiciary Committee's Subcommittee on Antitrust began a series of hearings that would run through 2006. These hearings had a specific spark: the *Times* articles, complaints by small suppliers that GPOs were plagued by conflicts of interest, the barriers GPOs allegedly posed to new suppliers getting access to hospital markets, and the barriers faced by clinicians and patients getting access to the new technologies offered by these suppliers.

The first Senate hearing focused on whether GPOs inhibited competition and market entry in various medical device markets, negotiated favorable prices for themselves rather than hospitals, and had financial interests with the suppliers they contracted with.¹²⁷ As summarized by Senator Kohl in his opening remarks, the question was whether or not GPOs served the interests of hospitals and patients? Did they offer a wide choice of products available for purchase at reduced costs, or did they serve their own interests in the form of reduced choice of products (by virtue of discouraging innovation and new supplier firm entry) procured at high costs (that would increase their CAFs)? Such fees were portrayed during the hearings as payments by large incumbent suppliers to GPOs to exclude small, new competitors from the marketplace by virtue of denying them access to GPO contracts. Representatives from the National Venture Capital Association (NVCA) went further by claiming GPOs discouraged private investment in medical device firms by virtue of blocking their access to selling products to hospitals. Representatives from the Medical Device Manufacturers Association (MDMA) also opined that small firms developed most of the innovative products in medical devices, equipment, and diagnostics. These firms were systematically blocked from gaining market uptake for their products by sole-source and dual-source contracts GPO contracts (that favored large

manufacturers), and by GPO contracts that bundled multiple products together (that favored large, diversified manufacturers).

GPO Industry Response: HIGPA Code of Conduct

In response to the hearing, the HIGPA trade association agreed to implement a code of conduct for its members to foster greater transparency, particularly in their purchase of physician preference items (PPIs). Medical devices, including those made by small manufacturers represented by MDMA, constituted one important category of PPIs. The HIGPA Code established baseline principles for GPOs to adopt, recognizing that both individual GPOs and the industry as a whole had important responsibilities (see Appendix II). For example, there were certain issues pertaining to individual GPO business practices -- such as the level of administrative fees -- that HIGPA could not address without being in violation of federal antitrust laws. The HIGPA Code also sought to address three major concerns expressed by Senator Kohl in the Senate hearings: conflicts of interest, contracting practices, and cost savings.

Going beyond the Code of Conduct, the individual GPOs also developed their own ethical codes.¹²⁸ One large GPO (Premier) adopted additional principles to regulate its contracting behavior and address issues the Code could not deal with. Premier also commissioned a report by a business ethicist to identify the best ethical standards for GPOs.¹²⁹ Those standards, which incorporated and extended those found in the Industry Code, were presented to Premier in October 2002. Premier's board immediately adopted the report, committed to implement its 50 recommendations, and then released it to assist other GPOs and supply chain participants. The author of the report, Professor Kirk Hanson, commented that the ethical analysis undertaken by Premier was rarely found in industry.

Senate Hearings July 2003

The next set of Senate hearings in July 2003 followed up on issues from the first hearing -- specifically whether the GPOs' voluntary code of ethics was working and what efforts

had been undertaken to ensure competition and innovation in product markets.¹³⁰ The former issue was characterized as the low-hanging fruit, where some progress had been made; the latter issue was viewed as more critical and with less progress made. These hearings further investigated the contracting process by discussing “bundled sole-source contracts,” whereby the GPO negotiated to buy a diverse bundle of products from one supplier. GPO critics claimed such contracts were anticompetitive by excluding smaller manufacturers who made product lines narrower than the bundle/portfolio obtained from a single, large, and diversified vendor. The hearings also considered the impact of the high purchase commitment levels hospitals needed to meet to get the best price. By virtue of meeting the high commitment levels on sole-source or dual-source contracts, it was argued, hospitals had little money left to spend on purchases from smaller, innovative suppliers not on the GPO contract (what became known as “low headroom”).

The GPOs countered during the hearings that (a) they were shifting many of their contracts to multi-source arrangements, (b) they entered high commitment contracts when their hospital members wanted them to, (c) many of the purchases made by their hospital members were not under GPO contracts, (d) contracts also included an “open tier” where hospitals could buy as much or as little as they desire, and (e) they had reduced the scope of product bundling in several areas.

Senate Hearings September 2004

A third set of Senate hearings held in September 2004 focused on possible legislative remedies if self-regulation and voluntary codes of conduct were deemed insufficient.¹³¹ Senator Kohl discussed the possible need for legislation to mandate and make permanent the voluntary changes undertaken by GPOs once the spotlight of Senate hearings had been removed. Other experts testified that the reforms they had undertaken were voluntary, non-uniform, reversible, non-enforceable, carried no penalties for non-compliance, and had not in fact worked.

During the hearings, many of the same criticisms leveled against the GPOs during the earlier hearings were repeated. These included: (a) GPOs served as barriers to market entry by new suppliers, which impeded innovation and raised product prices; (b) GPOs were the agents of large incumbent suppliers; and (c) CAFs facilitated the joint contracting between GPOs and these large suppliers. The hearings also yielded testimony that the GPO code of conduct only applied to physician preference items, and not to commodity items where traditional GPO contracting practices (sole-source, bundling) were allowed to continue, as well as claims that product selection decisions were being taken out of the hands of clinicians and made by non-clinicians (e.g., GPO product committees that could not represent the interests of thousands of doctors and nurses in GPO member hospitals).

The next month, Senators Kohl and DeWine, the ranking members on the Subcommittee, proposed a new piece of legislation called The Medical Device Competition Act (Senate Bill 2880). This Act would require the Department of Health & Human Services (DHHS) to oversee GPO activities, ensure that GPOs conformed with principles of ethical conduct and competition, and limit the CAFs that GPOs could charge. The Act added two new requirements to the criteria for exemption from criminal penalties for violating the anti-kickback statute (AKS, see footnote 3): (1) the contracting, business, and ethical practices of the purchasing agent be not inconsistent with regulations to be promulgated by the Secretary of DHHS; and (2) the purchasing agent be certified to be in compliance with such regulations.

The Act directed the Secretary of DHHS to promulgate regulations specifying the contracting, business, and ethical practices of an authorized purchasing agent that are contrary to antitrust law and competitive principles, to ethical standards, or to the goal of ensuring that products necessary for proper patient care or worker safety are readily available to physicians, health care workers, and patients. The bill also restricted the amount of fees paid to purchasing personnel or GPOs to 3 percent of the purchase price of goods or services provided by contract vendors. It also restricted fees to include "only

those reasonable costs associated with the procurement of products and the administration of valid contracts" and would not include "marketing costs, any extraneous fees or any other payment intended to unduly or improperly influence the award of a contract based on factors other than the cost, quality, safety or efficacy of the product."

GPOs objected to the calls for regulation and proposed further methods to regulate their own conduct. Specifically, in 2005, nine large GPOs and HIGPA formulated the Hospital Group Purchasing Industry Initiative (HGPII) and a methodology to ensure the changes already being implemented would be sustained and become a permanent way of doing business. HGPII followed three main tenets: promote an "ethical culture of compliance," promote self-governance and commitment to ethical standards by GPO leadership, and share best practices in dealing with issues of ethics and business conduct. To achieve these aims, the GPOs pledged to adhere to six ethical principles (e.g., written code of business conduct, develop a more open and competitive purchasing process free of conflicts of interest), to report annually to the public on adherence to these principles via a "Public Accountability Questionnaire," and participate with other GPOs in an annual best practices forum (see Appendix III). To allow this voluntary and self-regulatory approach to work, Senators DeWine and Kohl held off introducing their proposed legislation.

Senate Hearings March 2006

A fourth set of Senate hearings in March 2006 sought to determine whether such voluntary and industry-led efforts were (a) effective in promoting competition, and (b) sufficient in doing so.¹³² As before, the overall objective of the hearing (and the Senate Subcommittee) was to ensure competition in the markets connecting product suppliers with hospital buyers as mediated by the GPOs. As stated by Senator Mike DeWine in his opening comments, the voluntary codes of conduct adopted by each of the major GPOs two years before seemed to have improved the contracting scene and market access for small suppliers. But were the industry's own voluntary reforms undertaken to date

sufficient? Had the HGPII initiative been successful? Or were other steps needed to reinforce them? Such steps included passage of the Medical Device Competition Act, the proposed Ensuring Competition in Hospital Purchasing Act which would have repealed the safe harbor for GPOs and their collection of CAFs, and the Hospital Group Purchasing Act which would have imposed new ethics and best practices on GPOs and created a federal compliance office to oversee them. In the end, the solution needed was to balance access by clinicians and the public to new innovative technologies with the need for cost containment using GPOs.

During the hearing, the HGPII Coordinator stipulated the initiative was off to a successful start with the enthusiastic support of the GPOs, as evidenced by the public accountability process (GPO posting of questionnaires on the web, and the number of visits to these websites). By contrast, the Executive Director of the MDMA testified the GPOs had not corrected their practice of exclusionary contracts - - e.g., using bundles of unrelated products, using long-term sole-source contracts, the awarding of no-bid contracts, collection of high CAFs, and preference for large incumbent suppliers that excluded smaller innovative suppliers. Evidence to support such claims was limited to anecdotal testimony from an antitrust case in the courts, and a GAO report (see below) that GPOs kept a portion of their CAFs rather than distribute them all back to their hospital members. A third witness testified that the HGPII effort failed to meet rigorous standards for industry-developed codes of conduct and compliance with ethical practices, and thus that there were no real objective means to monitor and verify GPO practices.¹³³ A fourth and final witness, a hospital CEO from Senator DeWine's home state of Ohio, testified that GPOs saved her hospital money on product purchases. She also stated that the portion of the CAFs retained by the GPO went towards supplier contracting efforts that helped her hospital to reduce their operating costs (e.g. staffing levels). Finally, she stated their GPO accounted for nearly two-thirds of their supply spending, leaving more than one-third of that spending done by the hospital based on clinician preferences (and without any GPO mediation). Whether or not a small vendor could convince her hospital to contract for its product rested on how well it did to convince clinicians in vendor fairs.

Appendix II

2002 HIGPA Code of Conduct

According to a HIGPA news release on June 30, 2002, HIGPA's Code of Conduct Principles were designed to strengthen the delivery of health care products and services by creating a set of principles for GPOs to incorporate into their businesses.¹³⁴ These included:

- * Eliminating potential conflicts of interests;
- * Ensuring open communications between members and vendors;
- * Establishing guidelines for the use of contracting tools;
- * Creating a code of conduct certification program;
- * Appointing a code of conduct compliance officer at each GPO;
- * Establishing reporting and education programs, including surveys to quantify the value of GPOs; and,
- * Requiring full disclosure to members of all vendor payments.

The HIGPA Code of Conduct Principles sought to address three major concerns expressed by Senator Kohl in the first Senate hearings in April 2002: conflicts of interest, contracting practices, and cost savings. According to the release, the Code addressed the three major concerns as follows:

Prohibiting employees who are in a position to influence the GPO's contracting decisions from accepting any gifts, entertainment, favors, honoraria, or personal services payments (other than those of nominal value) from any participating vendor;

Prohibiting employees who are in a position to influence the GPO's contracting decisions from having an equity interest in any participating vendor;

Requiring GPO non-employees, officers, directors or advisors who are in a position to influence the GPO's contracting decisions to disclose any gifts, entertainment, favors, honoraria, or personal services payments they

receive from participating vendors and be recused from any negotiations or decisions relating to such participating vendor;

Requiring GPO non-employees, officers, directors or advisors to disclose any equity interests in any participating vendor and be recused from any negotiations or decisions relating to such participating vendor;

Prohibiting a GPO from having a corporate equity interest in any participating vendor of clinical products or services, unless the acquisition of the equity interest demonstrably benefits the GPO's members by creating a source of a clinical product or service where there is no other source, or very limited sources;

Requiring each GPO to permit its members to (a) communicate directly with all vendors (b) assess products or services provided by all vendors and (c) purchase clinical preference products or services directly from vendors that do not contract with the GPO;

Requiring that, to the extent contracting tools are used, either alone or in combination, in contracting arrangements, each GPO consider a set of specific factors -- such as the occurrence of innovation in the product category and the market share of relevant vendors -- to achieve a high quality of care and competitive pricing;

Requiring each GPO to implement a contracting process that (a) informs potential vendors of the process for seeking and obtaining contracts with the GPO and (b) provides all interested vendors with the opportunity to solicit contracts;

Requiring each GPO to individually engage in, or otherwise participate in, processes and programs that routinely evaluate, and provide opportunities to contract for, innovative clinical products or services; and

Requiring each GPO to adopt policies and procedures that endeavor to address vendor grievances related to access for innovative clinical products or services.

To deal with the issue of cost savings achieved through GPOs, the Code of Conduct committed to support the production of authoritative surveys and studies that would provide the public with reliable and up-to-date information on the value of GPOs. In addition, according to the release, the Code addressed other issues, including some of those advanced by other health care trade associations, such as:

Requiring GPOs to appoint a compliance officer who would be responsible for overseeing compliance with the Code and the fulfillment of the GPO's reporting requirements;

Requiring each GPO member of HIGPA to certify annually to HIGPA that it was in compliance with the principles. HIGPA would publish an annual report identifying those HIGPA members that have certified their compliance. This certification would constitute a requirement for membership in HIGPA;

Creating and supporting a web-based directory where vendors could post product information, including information about products that the vendors consider to be new and innovative;

Requiring full disclosure to a GPO's members of all vendor payments, including those payments that were not allocable to the actual purchase of a member; and

Requiring GPOs to offer or participate in programs that promoted diversity among vendors to include women and minority-owned vendors.

Appendix III

2005 HGPII Code of Conduct¹³⁵

HGPII sought to assure ongoing adherence to ethical conduct and business practices, and to hold the confidence of the public and the Government in the integrity of the industry. For purposes of the antitrust laws, however, it is critical to distinguish between competitive bidding practices that result in certain vendors failing to win contracts and exclusionary practices that result in foreclosure of an entire market in which a particular product is sold, thereby reducing consumer welfare. In somewhat different terms, while GPO contracting practices may result in commercial disappointment for certain vendors, it is important that in most instances they do not injure competition.

Members of HGPII pledge to:

1. Establish a process for the industry to improve and monitor its ethical and business conduct practices through significant transparency and to sustain a high level of trust with the public.
2. Follow the six core ethical and business principles:
 - a. have and adhere to a written code of business conduct. The code establishes high ethical values and sound business practices for the signator's group purchasing organization.
 - b. train all within the organization as to their personal responsibilities under the code.
 - c. work toward the twin goals of high quality healthcare and cost effectiveness.
 - d. commit itself to work toward an open and competitive purchasing process free of conflicts of interest and any undue influences.
 - e. have the responsibility to each other to share their best practices in implementing the Principles; each Signatory shall participate in an annual Best Practices Forum.
 - f. be accountable to the public
3. Report annually on adherence to these principles using an Annual Public Accountability Questionnaire
4. Participate in the Annual Best Practices Forum to discuss best ethical and business conduct practices with other GPO representatives and interested parties.

For instance the 2011 forum included sessions on expanding business opportunities for small, disadvantaged, and diverse vendors, trends in organizational ethics, current health care policy and legislative issues, and compliance programs. This forum also included a panel of representatives from six vendors who spoke about their experiences with GPOs.

The Initiative also formed an independent Advisory Council, with participants from outside the GPO industry, to provide a source of independent advice and counsel to a steering committee charged to build trust with the public and promote legal compliance and high ethical standards and achieve accountability. The principal mechanism for accountability is the annual accountability questionnaire that is available to the public and “used by the Initiative Coordinator to compile a summary report on the adherence of those signing to participate to the Principles and a report on evolving Best Practices in fulfillment of the Principles.” The questionnaire requests that each GPO describe:

1. The key components of the GPO’s written code of business ethics and conduct. (Please provide a copy and describe any changes since the last submission.)
2. The GPO’s policies and procedures that address conflicts of interest for all employees and clinical advisory members in a position to influence contracting decisions and for all other employees and members of the Board of Directors and/or the GPO’s governing body.
3. The GPO’s policies and procedures that address activities, including other lines of business of the GPO and the GPO’s parent company or affiliates, that might constitute conflicts of interest to the independence of its purchasing activity.
4. The GPO’s policies with regard to disclosing to customers money or value received from vendors, whether in the form of administrative fees, marketing fees, partnership incentives, equity or any other form.
5. If it discloses to each customer all fees, in any form, paid to the customer organization?
6. The GPO’s policy with regard to whether all responsible vendors are eligible to compete and receive a contract award under the criteria.
7. The GPO’s publicly available policy and procedure that addresses vendor rights, including a procedure for vendor grievances.
8. The GPO’s policy and process to evaluate and provide opportunities to contract

- for innovative clinical products and services.
9. The GPO's program or activities that encourage contracting with small, women-owned and minority businesses.
 10. Whether and in what manner the GPO distributes its written code of business ethics and conduct to all applicable employees, agents, contractors, clinical advisory committees, and others involved in group purchasing activity.
 11. How new employees involved in group purchasing are provided an orientation to the written code of business ethics and conduct.
 12. The nature and content of the GPO's annual employee refresher training on the written code of business ethics and conduct.
 13. The mechanism (e.g., a corporate review board, ombudsman, corporate compliance or ethics officer) for employees to report possible violations of the written code of business ethics and conduct to someone other than one's direct supervisor, if necessary.
 14. The mechanism the GPO utilizes to follow up on reports of suspected violations to determine what occurred and who was responsible, and to recommend corrective and other actions.
 15. How the GPO employees' compliance with its written code of business ethics and conduct is measured in their job performance?
 16. The processes the GPO utilizes to monitor, on a continuing basis, adherence to the written code of business ethics and conduct, and with applicable federal laws.
 17. How the GPO fulfilled its obligation to participate in the most recent Best Practices Forum.
 18. How the GPO reports to the company's Board of Directors or its Audit or other appropriate committee on the GPO's ethics and compliance program and its commitment to the Initiative's Principles.
 19. The senior manager assigned responsibility to oversee the business ethics and conduct program.

Footnotes

¹ Lawton Burns and David Cassak. *The Role of Group Purchasing Organizations (GPOs) in the Health Care Value Chain*. Unpublished report.

² Paul Starr. *The Social Transformation of American Medicine*. (New York, Basic Books, 1982).

³ In the mid-1980s, some hospital suppliers complained that the GPOs' reliance on reimbursement from suppliers (in the form of contract administration fees, or CAFs) represented kickbacks that might violate the Anti-Kickback Statute (AKS) enacted as part of the 1972 Social Security Amendments (Public Law 92-603) and now codified at section 11288(b) of the Social Security Act. The Office of the Inspector General inside the Department of Health & Human Services (OIG-DHHS) concluded that while the CAFs were a technical violation of the AKS, they should nevertheless be allowed to continue since GPOs helped hospitals to jointly negotiate lower prices than they could negotiate individually based on volume purchasing, and thus to lower their supply costs. The OIG also opined that DHHS encouragement of marketplace competition encompassed hospital use of GPO agents. The U.S. Department of Justice did not take a position on the matter, but suggested that Congress clarify what was permissible behavior. That action came the following year in the 1986 Omnibus Budget Reconciliation Act (OBRA). OBRA included an amendment to the Social Security Act (section 1877) which legitimized vendor payments to GPOs acting as agents to providers of services to Medicare patients, provided there was (a) a contractual agreement stipulating the amount of the payment and (b) proper disclosure of such payments to DHHS when requested. One year later, Congress passed the Medicare and Medicaid Patient and Program Protection Act (1987), which authorized the Secretary of DHHS to issue "safe harbor regulations" that specified which payment and business practices in technical violation of the AKS were not harmful to Federal health care programs and might encourage beneficial arrangements. The Act also expanded the protection of GPO payments from AKS violation that met certain conditions for both Medicare and Medicaid patients. DHHS proposed its safe harbor rule in January 1989; the rule was finalized two years later in July 1991. Vendor payments to GPOs as CAFs did not violate the AKS as long as there was a vendor-GPO contract, the contract stated the vendor would pay the GPO a CAF of 3% or less of the purchase price, and the contract specified what the amount was when the CAF exceeded 3%. This review is based on the work of Richard Kusserow and Thomas Herrmann. *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 Healthcare Supply Chain Association (Washington, D.C.). (Alexandria, VA: Strategic Management, March 22, 2013).

⁴ Walt Bogdanich, "Medicine's Middlemen: Questions Raised of Conflicts at 2 Hospital Buying Groups," *New York Times* (March 4, 2002), 1. Mary Walsh "When a Buyer for Hospitals Has a Stake in Drugs it Buys," *New York Times* (March 26, 2002). Barry Meier. "Hospital Products Get Seal of Approval at a Price," *New York Times* (April 23 2002). Mary Walsh. "Hospital Group's Link to Company is Criticized," *New York Times* (April 27, 2002). Mary Walsh and Barry Meier. "Hospitals Sometimes Lose Money by Using a Supply Buying Group," *New York Times* (April 30, 2002). Mary Walsh. "A Mission to Save Money, A Record of Otherwise," *New York Times* (June 7, 2002). Barry Meier and Mary Walsh. "Questioning \$1 Million Fee in Needle Deal," *New York Times* (July 19, 2002). Mary Walsh. "Accusation of Conflicts at a Supplier to Hospitals," *New York Times* (August 1, 2002). Barry Meier and Mary Walsh. "Buying Group for Hospitals Changes Ways," *New York Times* (August 6, 2002). Barry Meier and Mary Walsh. "Buying Group for Hospitals Vows Change," *New York Times* (August 9, 2002). Mary Walsh. "3 Medical Supply Companies Receive U.S. Agency Subpoenas," *New York Times* (August 15, 2002). Barry Meier. "A Persistent Small Supplier Gets Contract for Hospitals," *New York Times* (September 4, 2002). Barry Meier. "A Region's Hospital Supplies: Costly Ties," *New York Times* (October 8, 2002). Barry Meier. "Ethics Standards Overhaul Urged for Hospital Buying Groups," *New York Times* (October 24,

2002). Mary Walsh. "More Hospitals Change the Way They Buy Drugs and Supplies," *New York Times* (December 28, 2002).

⁵ John Jones, "Benefits of Physician-owned Group Purchasing Organizations," *Physician's News Digest* (October 2005). Available online at: <http://www.physiciansnews.com/2005/10/13/physician-owned-group-purchasing-organizations/>

⁶ United States Senate. *Physician Owned Distributors (PODs): An Overview of Key Issues and Potential Areas for Congressional Oversight*. An Inquiry by the Senate Finance Committee Minority Staff (June 2011).

⁷ Booz and Company. *GPO Market: Abstract of Findings*. (New York, NY: Booz, June 2008).

⁸ For example, see "The Premier Healthcare Alliance Emerges," in Linda Swayne, W. Jack Duncan, and Peter Ginter, *Strategic Management of Health Care Organizations*. (San Francisco, CA: Jossey-Bass, 2008).

⁹ Lawton R. Burns. *The Health Care Value Chain: Producers, Purchasers, and Providers*. (San Francisco, CA: Jossey-Bass, 2002).

¹⁰ Lawton R. Burns. Presentation to U.S. Senate and House of Representatives Staffers. (January 2013).

¹¹ Eugene Schneller and Larry Smeltzer. *Strategic Management of the Health Care Supply Chain*. (San Francisco, CA: Jossey-Bass, 2006).

¹² Effective July 7, 2004, the GAO's legal name was changed from the General Accounting Office to the Government Accountability Office. The GAO acronym applied to each.

¹³ U.S. General Accounting Office, *Group Purchasing Organizations: Pilot Study Suggests Large Buying Groups Do Not Always Offer Hospitals Lower Prices*, GAO-02-690T. (Washington, DC: April 30, 2002).

¹⁴ General Accounting Office. *Group Purchasing Organizations: Use of Contracting Processes and Strategies to Award Contracts for Medical-Surgical Products*. GAO-03-998T. (July 16, 2003).

¹⁵ Eugene Schneller. *The Value of Group Purchasing – 2009: Meeting the Need for Strategic Savings*. (Tempe, AZ: Arizona State University, 2009).

¹⁶ The Lewin Group. *Assessing the Value of Group Purchasing Organizations*. (Washington, D.C.: Lewin Group, May 2003).

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