"White Paper: (Draft) A Cost Analysis of the 1987 Medicare Anti-kickback Safe Harbor for Group Purchasing Organizations and Pharmacy Benefit Managers"

Jan. 20, 2019

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Introduction

Before delving into the details and documentation on how hospital group purchasing organizations (GPOs) inflate the cost of drugs, devices, and supplies for hospitals, clinics, and alternate care facilities, I'll make several general comments. All of the documents to which I refer below are posted on our website, www.physiciansagainstdrugshortages.com or in links in this document.

First, the original and sole purpose of a GPO was to save money for these facilities by buying in bulk. This nonprofit, co-op model worked fine for nearly 80 years. Then in 1987 Congress passed the Medicare anti-kickback "safe harbor" provision, which exempted GPOs from criminal penalties for taking kickbacks and rebates from suppliers. After the Department of Health and Human Services Inspector General (HHS-OIG) implemented the "safe harbor" rules in 1991, GPOs became for-profit entities. While they claim that they provide other services to hospitals, the vast majority of their revenue is derived from "administrative," marketing, advance, conversion, rebates, prebates and other remuneration (a/k/a "legalized" kickbacks) re-

lated to their purchasing operations. Additionally, GPOs have acknowledged that they charge distributors up to 3% of transaction volume. The GPOs have also created a distribution oligopoly comprising three major distributors: McKesson, AmerisourceBergen, and Cardinal. Generally, only the "Big Three" GPO-authorized distributors are permitted to receive manufacturers' rebates, thereby restricting competition in this segment of the supply chain.

Second, the implementation of the safe harbor created perverse financial incentives that encouraged GPOs to "negotiate" higher rather than lower prices for healthcare supplies. That's because GPO revenue is calculated as a percentage of total sales volume (units sold X price per unit). Instead of serving as the agents of hospitals, GPOs got into the business of selling market share to healthcare facilities in the form of exclusive, sole-source contracts. The more market share the supplier wants, the more money it has to pay the GPO. By eliminating competition, these practices drive up prices. In 2003, the HHS-OIG quietly extended safe harbor protection to pharmacy benefit managers, thereby "decriminalizing" drug maker rebates. This gave rise to an unceasing upward spiral in the prices of drugs sold to individuals by PBMs.

Third, for the last 20 years, the GPO industry has been unable to present any independent, objective data or studies showing that they save hospitals money. Its claims of cost savings are based entirely on so-called "sponsored research studies" by ethically-challenged academics and consulting firms, bought and paid for by the Healthcare Supply Chain Association (HSCA), the GPO trade group, or its predecessor. In fact, the most recent such "study," published in June 2017, was co-authored by former Federal Trade Commission chairman Jonathan Leibowitz, who had ignored a November 2011 request by five United States senators to investigate anti-competitive GPO practices. It was nothing more than a regurgitation of several of the earlier bogus "studies" commissioned by the GPO trade group.

The fact that GPOs do not produce any savings at all for hospitals was underscored in 1) a bipartisan May 2, 2003 letter from Senators Mike DeWine (R-OH) and Herb Kohl (D-WI), then chairman and ranking member, respectively, of the Senate Antitrust Subcommittee, to then-Secretary of Defense

Donald Rumsfeld warning him against outsourcing DOD health supplies procurement to a GPO; and 2) a 2010 Senate Finance Committee report commissioned by Sen. Charles Grassley (R-IA). Senators DeWine and Kohl wrote: "…the savings figures GPOs frequently cite as benchmarks to demonstrate savings are based on a manufacturer's list price that hospitals rarely, if ever, pay." Similarly, Senator Grassley's report found that there were no independent empirical data whatsoever to support GPO claims of cost savings.

Fourth, the evidence will show that the GPO industry has used its considerable financial and political clout to block efforts by members of Congress and the Government Accountability Office (GAO) to conduct a comprehensive empirical analysis of the impact of the anti-kickback "safe harbor" on the prices of drugs, devices, and supplies. That's because the industry knows it could not survive a thorough, independent audit. The most flagrant example of the GPO industry's interference occurred in connection with a November 15, 2012 request by then-Rep. Ed Markey and five House colleagues for a GAO study on the role of GPOs in causing the shortages and the fungal meningitis outbreak, as well as an analysis of the budgetary impact of the safe harbor. Even though the GAO initiated the study, the final report of November 2014 did not address any of those issues. The GPO lobby derailed it.

Further, it would be virtually impossible for a non-government organization to conduct a comprehensive, independent audit comparing GPO and non-GPO prices because there is simply no transparency in the prices of healthcare supplies. There are no databases that enable systemic apples-to-apples price comparisons across the full spectrum of these goods. That is no accident. The GPOs have lobbied hard to keep it that way.

Finally, despite the absence of a comprehensive government cost/benefit analysis on the safe harbor, there is an abundance of other empirical and anecdotal evidence, which I have gathered over nearly two decades, that indicates that the GPO "pay-to-play" model actually inflates the annual cost of 1) drugs, devices and supplies sold through GPO contracts by an estimated $100 billion; and 2) drugs sold through PBMs by at least $130 billion, or at least 25% to 39%, for a total of about $230 billion for both middlemen combined. What follows is an explanation of how these consensus

estimates were determined. The examples cited are by no means comprehensive.

Part I: The Myth of GPO "Savings"

Empirical Studies. Two empirical studies have found that GPOs actually inflate the cost of healthcare supplies.

- The first, a 2002 report by what is now the Government Accountability Office, was entitled "Pilot Study Suggests that Large Buying Groups Do Not Always Offer Hospitals Lower Prices." In fact, in comparing GPO prices for devices with those negotiated directly by hospitals with manufacturers, the GAO investigation found that GPO prices for certain devices were sometimes 39% higher than non-GPO prices.

- Another empirical study was first released in 2010 by economists Hal Singer and Robert Litan and republished a year later in the *Journal of Contemporary Health Law and Policy.* It was funded by the Medical Device Manufacturers Association (MDMA), a trade group of entrepreneurial medical device makers that has lobbied Congress to repeal the anti-kickback "safe harbor." Using data on GPO and non-GPO prices of capital equipment provided by a company that advised hospitals on such purchases, the Singer/Litan study concluded that the anti-kickback statute inflated prices by about 15% for 2010, the last year they examined. It argued that this finding could be extrapolated to include all supplies purchased through GPOs. If that were the case, then about $30 billion could be saved by repealing the safe harbor, based on a low ball estimate of $200 billion in GPO contract volume for 2010. However, 15% is arguably a conservative number for capital equipment, since price comparisons for big ticket equipment tend to be easier than for the thousands of smaller healthcare supplies. Several years after the publication of the Singer/Litan article, Premier Inc., one of the two largest GPOs, bought MEMdata, the company that had supplied the transaction data. According to Dr. Singer, Premier has deactivated the company. The kind of comparative data MEMdata provided is no longer available, to the best of my knowledge.

Excess Fees. Under the "safe harbor" rules issued in 1991 by the HHS-OIG, GPO "administrative" fees were to be capped at 3%. If they exceeded that amount, the GPOs were to report them to member hospitals. The OIG was also empowered to request them. To circumvent that cap, the GPOs invented many other fees, notably marketing, advance, conversion, and licensing "fees," not to mention rebates and pre-bates. They have never voluntarily disclosed these fees, and a 2012 GAO report found that for years the OIG had exercised virtually no oversight over the industry. The industry has claimed for years that "admin" fees have not exceeded 3%, but the available evidence shows that ***total*** fees for a given product have sometimes exceeded 50% of its annual net revenue.

One glaring example is the 56.25% "fee" Novation demanded in 1998 of Ben Venue Laboratories for permitting BVL to market diltiazem to its member hospitals. This information is found in the "Excess Fee Reports" that Novation LLC (now Vizient) produced for 1998, 1999, and 2001 in response to a request from the Senate Antitrust Subcommittee. These reports were later obtained through discovery in a federal whistleblower lawsuit against Novation and other defendants. To be sure, this information is dated, but it still highlights the real intent of the GPOs: to enrich themselves, not save money for hospitals.

Keep in mind too that the anticompetitive impact of these fees on prices is likely to be far greater than the amount of the fees themselves. That's because the suppliers pay the fees in return for exclusive contracts that protect them from competition. Not surprisingly, Ben Venue shut down in late 2011 because it could no longer afford to maintain plant and equipment. That led to a global shortage of generic chemotherapeutic agents.

More evidence that GPO "fees" exceed the 3% limit is seen in a 2012 bio sketch of Novation's Ross Day, a pharmacy contracting director. He revealed, perhaps inadvertently, that average vendor fees on one of his drug portfolios amounted to 7.3% of total contractual volume, more than twice the prescribed limit.

Private Labeling. This is yet another mechanism that GPOs use to boost their profits by increasing prices of generic drugs and other supplies. Vizient uses the NOVAPLUS brand name, whereas Premier Pro Rx is Premier's generic drug private label. In a 1999 op-ed in the *Dallas Business Journal,* Tom Shaw, CEO of Retractable Technologies, a Texas maker of safety syringes, revealed that he rejected Novation's proposal to put its NOVAPLUS label on his patented safety blood-tube holder and increase its price to ***its own members*** from 27 cents to $1.00, a 270% markup. The 2010 Grassley report stated: "Two of the GPOs reported that they charge fees for use of their private label, which allows a manufacturer's products to be sold under the GPO's brand name." Because of the lack of price transparency, we can't prove beyond any doubt that the GPO private labelling programs raise all prices to this extent. But based on the available evidence, we believe that 30%-40% is a conservative estimate.

Savings by Hospitals that Sever GPO Ties.

- Iowa Health System, reported 12-14% immediate savings by dropping Premier, expected that to grow to 30-40%, according to *New York Times* of April 30, 2002
- Virtua Health, New Jersey. Unspecified savings. *New York Times*, April 30, 2002.

Price Declines Following New Market Entrants (competition).

For years, Masimo Corp., a, Irvine, CA maker of an innovative pulse oximeter, was locked out of the hospital market by sole-source contracts the major GPOs had awarded to the dominant supplier, Tyco/Nellcor—even though Masimo's superior product was more than 30% cheaper. Then in 2002, the Masimo story appeared on page one of the *New York Times* and its CEO testified on anticompetitive GPO practices before the Senate Antitrust Subcommittee. As a result, the GPOs awarded the company contracts. Shortly thereafter, Masimo filed an antitrust lawsuit against Tyco/Nellcor. As soon as Masimo was able to market its product, prices of ***all*** pulse oximeters dropped by 30%, according to Masimo. In his 2002 paper, "The Exclusion of Competition for Hospital Sales Through Group Purchasing Organizations," Harvard Law School Professor Einer Elhauge suggested that savings of 30% or more might be typical: http://nebula.wsimg.com/

7149083119b27346b88cd7fcadf6f3a7?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

In fact, in the mid-2000s, I conducted separate interviews with two former GPO contracting officers who did not know each other. One was Ms. Cynthia Fitzgerald, who was fired by Novation for questioning the GPO's unethical practice, and the other was Ms. Diana Smith, a contracting officer for Broadlane who quit for similar reasons. When I asked them how much could be saved by eliminating the GPO kickbacks, each immediately replied, "30%." Ms. Fitzgerald was the subject of a lengthy profile in *The New York Times* of Nov. 18, 2007, "Blowing the Whistle, Many Times." Ms. Smith was quoted extensively on GPOs in "Dirty Medicine," in the *Washington Monthly* of July-Aug. 2010.

Savings from Off-Contract Purchasing.

- Pacemakers: up to 39%, according to GAO report of April 30, 2002
- Garbage bags: 20% or more, *New York Times* of Aug. 1, 2002
- Chemotherapy agents, UCLA cancer clinics, 6%, *Los Angeles Times*, Feb. 17, 2005
- Medtronic, pacemakers, unspecified savings, *Wall Street Journal*, Feb. 25, 2011
- Propofol, 2017, 60%, based on price of $55 for a 10 vial box of propofol at a GPO-affiliated surgicenter in Illinois vs. $22 off-contract at a PA surgicenter (a rare instance in which we were able to compare GPO contract prices with off-contract prices for the exact same product)
- Over-the-counter medications and supplies: Up to 50% potential savings on Advil, bandages, cotton balls etc. from Costco vs. GPO contract prices, as reported by a retired nurse-manager at Harvard Vanguard Health
- Anesthesiology equipment & supplies: 25-35%, according to non-GPO authorized distributor in Philadelphia, PA who requested anonymity

Inflated Generic Drug Prices Resulting from Shortages/Lack of Competition.

As indicated in the table below, “Generic Drug Price Increases Due to Shortages/No Competition,” prices of generic injectable drugs have skyrocketed as a result of the shortages and lack of competition caused by anticompetitive GPO contracting and pricing practices. The drugs cited are a representative sample. Not shown is propofol, whose price surged more than 3000% because of the shortages.

Durable Medical Equipment (DME). In 2003, the Medicare Modernization Act required the Centers for Medicare & Medicaid Services (CMS) to change reimbursement for durable medical equipment (DME), including wheel chairs, oxygen tanks, infusion pumps, and the like, from a fee-based system to open competitive bidding. The reported results were dramatic. In 2012, CMS reported savings on a pilot program averaging 37% for all product categories and up to 47% for one category. We believe this is a reasonable proxy for the savings that could be achieved if the safe harbor were repealed and all healthcare supplies, including drugs, were purchased under an open competitive bid system**.** Attached is a CMS chart showing these savings.

Medical Wastage. In a statement submitted to the Senate Antitrust Subcommittee hearing of Sept. 14, 2004 on anti-competitive GPO practices, a Texas health care supplies distribution expert estimated that the healthcare supply chain produced about $6 billion [about $7.8 billion in 2018 dollars] in medical supply “wastage,” or “overstock," annually, largely because of the perverse incentives of the GPOs and their “symbiotic” relationship with manufacturers. Unlike virtually every other U. S. industry, big GPOs refuse to recycle perfectly good, unexpired, unopened supplies that are discarded in hospital dumpsters and incinerators. The reason, he said, is that the GPOs and manufacturers make money on discarded goods, and lose money on returned items. Another $700 million, he wrote, is spent disposing on these goods. In 2018 dollars, the total cost of wastage would be about $8.7 billion, or about 3% of GPO contract volume. The complete statement of Mark H. Wallis, CEO of Invatec, can be found in the transcript of the hearing, which is posted on the “Congressional Hearings” page of our website.

Non-Healthcare Industry Analogs. There are a number of non-healthcare examples of the savings that have been achieved after prosecutors have eliminated the kickbacks associated with criminal price-fixing schemes. The lesson here is that kickbacks are kickbacks, whether they are, like GPO kickbacks, blessed by Congress or are subject to criminal penalties, as they are in virtually every other American industry:

- The 1981 Oklahoma County Commissioners scandal, in which corrupt suppliers of asphalt and other road-building materials paid kickbacks to the commissioners for exclusive contracts. At the time, this was considered the largest kickback scandal in American history. According to former United States Attorney Bill Price, who prosecuted these cases in the early 1980s, prices of these materials plunged by about 40% after the indictments.

- New York State Organized Crime Task Force, New York City Construction Industry. Late 1980s. According to a former Task Force official, prices also dropped by about 40% following prosecutions of corrupt building contractors and suppliers.

Part II: How the Anti-Kickback Safe Harbor Inflates PBM prices

In contrast to GPOs, PBMs distribute drugs directly to individuals on behalf of health insurers, employers, union, Medicare Part D and other plans. Using rebates and other discounts, drug makers compete with each other for positions on PBM formularies, in much the same way that they and other suppliers use kickbacks and rebates to compete for exclusive, “sole-source" GPO contracts. In 2003, as previously noted, the HHS-OIG “decriminalized” PBM rebates by granting them the same “safe harbor” protection enjoyed by the GPO industry. This has led to an unceasing upward spiral in the cost of drugs sold by the PBM middlemen. That’s because drug makers continually raise their prices to offset the cost of the rebates. At a June 2017 hearing before the Senate HELP Committee, witnesses generally agreed that these rebates, which have been estimated at $130 billion annually, were unnecessary and could be eliminated.

Because of the lack of transparency on drug pricing, I am unable to determine the degree to which these rebates inflate PBM drug prices. Accordingly, I use a conservative estimate of $130 billion annually as a proxy for the added cost represented by PBM rebates.

Conclusion:

Based on the empirical and anecdotal evidence on how GPOs inflate the cost of drugs, devices, and supplies sold through GPO contracts, in addition to the PBM rebates, I estimate that repeal of the anti-kickback "safe harbor" provision would result in annual healthcare system savings of ***at least*** 25% to 39%, or roughly $230 billion. On the GPO portion, the savings to Medicare and Medicaid would amount to about $37 billion, since those federal programs cover about 37% of total annual healthcare expenditures, according to CMS. The savings to Medicare and Medicaid that might be achieved by eliminating the safe harbor for PBMs requires further analysis.

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January 20, 2019
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Generic Drug Price Increases Due to Shortages/No Competition

DRUG	Pre-Shortage Price	Current Price (5/1/17)	% Increase	Use/Treatment
Ephedrine	(per vial) $1.90	$31.94	1581	increases bp - shock situations
Furosemide	0.56	1.73	209	diuretic- congestive heart failure
Glycopyrrolate	1.02	7.06	592	decreases secretions during intubation
Isoproterenol	46.25	1136.73	2358	increases heart rate after cardiac surgery
Nitroprusside	45.53	253.64	457	decreases bp in seizures
Neostigmine	1.45	58.67	3946	treats myasthenia gravis
Norepinephrine	2.99	6.05	102	increases bp in shock situations
Sodium chloride	(per liter) 0.81	(substitute) 4.82	495	basic nutritional IV
Succinylcholine	1.04	17.32	1565	muscle relaxant used in surgery
Vancomycin 10gm	28.31	(substitute) 206.04	628	antibiotic-staph infections, MRSA
Vasopressin	0.94	126.22	13328	hormone- brain lesions
Verapamil	6.93	27.07	291	anti-hypertensive, arrhythmia

Note: Representative sample.

Sources: Premier Inc., McKesson Corp., Yankee Alliance, hospital pharmacy

ROUND 1 RECOMPETE WEIGHTED AVERAGE SAVINGS*						
Enteral Nutrients, Equipment and Supplies	External Infusion Pumps and Supplies	General Home Equipment and Related Supplies and Accessories	NPWT Pumps and Related Supplies and Accessories	Respiratory Equipment and Related Supplies and Accessories	Standard Mobility Equipment and Related Accessories	Overall Average
41%	21%	47%	42%	40%	34%	37%

' Weighted average savings based on weighted percentage reductions in Medicare allowed payment amounts for items in each product category.
Weights used in calculating average reductions were the same weights assigned to each code as part of the Request for Bids.

Weighted Average Savings by Competitive Bidding Area per Product Category

Competitive Bidding Area	PRODUCT CATEGORIES					
	Enteral Nutrients, Equipment and Supplies	External Infusion Pumps and Supplies	General Home Equipment and Related Supplies and Accessories	NPWT Pumps and Related Supplies and Accessories	Respiratory Equipment and Related Supplies and Accessories	Standard Mobility Equipment and Related Accessories
harlotte-Gastonia-Rock Hill, NC-SC	40%	13%	46%	42%	39%	31%
incinnati-Middletown, OH-KY-IN	42%	28%	46%	46%	39%	34%
leveland-Elyria-Mentor, OH	41%	23%	44%	43%	44%	32%
allas-Fort Worth-Arlington, TX	42%	14%	53%	46%	37%	34%
ansas City, MO-KS	41%	20%	43%	48%	41%	35%
liami-Fort Lauderdale-Pompano Beach, FL	38%	30%	43%	32%	34%	34%
rlando-Kissimmee-Sanford, FL	39%	22%	40%	35%	40%	34%
ittsburgh, PA	41%	21%	47%	42%	43%	37%
iverside-San Bernardino-Ontario, CA	43%	16%	56%	46%	46%	36%