Physicians Against Drug Shortages (PADS)

February 16, 2021

File Code: OIG-1117-N

Agency: Health & Human Services Office of Inspector General

Comments in response to solicitation of "Proposals and recommendations for developing new, or modifying existing, safe harbor provisions under section 1128B(b) of the Social Security Act (the Act), the Federal anti-kickback statute, as well as developing new OIG Special Fraud Alerts."

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Part I: Background: The Unsafe Anti-Kickback Safe Harbor

As executive director and co-founder of ***Physicians Against Drug Shortages***, a *pro bono* patient advocacy group, I appreciate the opportunity to comment on the harm inflicted on patients, clinicians, taxpayers and our health care system generally by the safe harbor for hospital group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs). My comments include recommendations for modifying the rules governing GPOs and PBMs.

Founded in 2012, PADS comprises about 120 healthcare practitioners, including physicians, pharmacists, and nurses, as well as concerned citizens. Our expanded coalition now includes several groups that together represent about 20,000 physicians. We organized PADS for one reason and one reason only: patients and their physicians no longer have access to affordable lifesaving medications. And since the COVID outbreak, they no longer have access to critical supplies, masks and other personal protection equipment as well.

Our mission is to end the chronic artificial shortages and skyrocketing prices of lifesaving drugs, devices and supplies, including personal protection equipment, by restoring integrity and market competition to the broken healthcare supply chain. That can only be *fully* accomplished by congressional repeal of the ill-conceived 1987 Medicare anti-kickback "safe harbor" for hospital group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs) [42 CFR 1001.952 (j)]. For nearly a decade, we have been working to expose the real root cause of this market failure and to prevail upon Congress and the relevant federal agencies to address it.

I've been involved in this issue at one time or another for more than two decades, initially as a financial journalist, later as an advocate for entrepreneurial medical device makers, and for the last decade, as a *pro bono* advocate for patients and clinicians who are no longer able to gain access to lifesaving drugs and supplies. My first article on the topic appeared in

BusinessWeek of March 16, 1998. It was entitled, “Locked Out of the Hospital.” Things have only gotten worse since then.

More recently, my PADS colleagues and I have written extensively on this issue, including op-eds in the *New York Times, Wall Street Journal, Barron’s, Baltimore Sun*, and many other national and regional general interest and health care publications. To read these and other articles, visit the “Media Reports” and “PADS in the News” pages of our website: http://www.physiciansagainstdrugshortages.com/articles-about-pads.html. It contains extensive documentation on these questionable practices, focusing on the role of GPOs in undermining competition and innovation in the healthcare supply chain thereby causing chronic shortages of generic drugs, and over the last year, masks and other personal protection equipment (PPE).

By exempting GPOs, and later PBMs, from criminal prosecution for taking kickbacks from suppliers, the anti-kickback “safe harbor” gave rise to a “pay-to-play” business model that has had a pernicious impact on patient care. It is arguably the most harmful healthcare statute ever enacted and represents an ongoing threat to the health and safety of all Americans. In a nutshell, Congress awarded these cartels a “Get out of jail free card,” creating a “legalized” fraud, and becoming the only industry in America, to the best of our knowledge, that has been granted such an exemption.

Frankly, we are incredulous that those responsible for enacting the safe harbor could have thought that kickbacks paid by suppliers to GPOs was an “innocuous business arrangement” that should be exempt from criminal penalties.

Indeed, Antitrust Division chief Makan Delrahim, in response to a question on GPOs by Sen. Richard Blumenthal (D-CT) at the Senate Antitrust Subcommittee oversight hearing of September 17, 2019, expressed deep concern about the harm GPOs were inflicting on our healthcare system.

Referring to the safe harbor, Mr. Delrahim said, that “…It’s created a situation where some of these GPOs are buying exclusivity at the risk of innovation, at the risk of cost, and at the risk of lives of patients.”

Sen. Blumenthal is well acquainted with this matter. As Connecticut attorney general, he investigated GPOs and a related slush fund and submitted a statement on his findings to the Senate Antitrust hearing of March 15, 2006 on GPO abuses, the fourth in as many years. In it, he referred to GPOs as an "an insidious, incestuous, insider system."

For nearly 80 years, until 1991, when the HHS-OIG promulgated the safe harbor rules, GPOs had operated according to a cooperative business model, similar to agricultural co-ops, the Harvard Co-Op, Recreational Equipment Inc. (REI), and even for-profit companies like Costco and Sam's Club. By all accounts, they had successfully performed their original and sole mission: saving money for their member hospitals by banding together to buy, in bulk, the best drugs, devices and supplies at the best prices. Under this arrangement, GPOs were the servants of hospitals. Administrative costs were covered by hospital dues.

The safe harbor created an inherent conflict of interest, transforming the co-op model into a "pay-to-play" scheme. GPOs got into the business of selling market share, in the form of sole-source contracts, to the highest bidder. Overnight, these cartels became the marketing agents for vendors, not the servants of hospitals. How do we know this? The GPOs have said so. As Lee Perlman, a top executive of the Greater New York Hospital Association (GNYHA), until early last year a GPO in its own right, told *Modern Healthcare* of February 10, 1997. "We basically delivered market share."

The safe harbor gave rise to perverse incentives in which higher prices for supplies generated more money (a/k/a kickbacks) for GPOs. That's because GPO revenue is based on a percentage of sales volume (price times units sold). So GPOs have a built-in incentive to maximize prices, not lower them. And that's exactly what they've done. Vendors compete for GPO contracts based on who can pay the biggest kickbacks, not who can supply the best product at the best price. GPOs are like the proverbial troll under the bridge. By paying the toll to the troll, dominant vendors gain exclusive access to thousands of GPO member hospitals and eliminate or squeeze competitors. GPOs perform no useful medical, social, or financial function. They don't perform research and development, manufacture, maintain inventory, or distribute goods. They are self-serving middlemen, the supply chain's gatekeepers and market makers.

As Professors Michael Porter and Elizabeth Teisberg wrote in their seminal 2006 book, *REDESIGNING HEALTH CARE*, "Most troubling is that some GPOs are funded by suppliers rather than solely by hospitals…Thus, buying groups may serve the interests of the suppliers that provide their funding, not providers, thereby undermining value-based competition. While the extent of this bias is contested, the potential for conflict of interest is indisputable." They added: "To enable value-based competition, every buying group practice should be consistent with open and fair competition. There is no valid reason for buying groups to accept financing or any payments from suppliers: if a buying group adds value, the customers (hospitals) should voluntarily pay for it."

Even GPO industry representatives have acknowledged the industry's conflicts of interest. At the Federal Trade Commission's November 8, 2017 workshop on drug market competition, Ms. Stephanie Trunk, a partner at Arent Fox, a law/lobbying firm for the Health Care Supply Chain Association (HSCA), the GPO trade group, told the gathering: "...GPOs are the purchasing agent of the member hospitals, and being paid by suppliers could represent a conflict of interest." As for the FTC, it has done nothing to address the anticompetitive abuses of GPOs. In fact, when I raised this with a senior FTC official at the conference, he said, "We don't have the resources. Go to Congress."

The evidence on anticompetitive GPO and PBM pricing and contracting practices, self-dealing, conflicts of interest, kickbacks, and sharebacks is overwhelming. It comprises four Senate Antitrust Subcommittee hearings, federal and state investigations, including Government Accountability Office, Health & Human Services, and Food and Drug Administration reports; major media exposés, notably the prize-winning 2002 *New York Times* "Medicine's Middlemen" series; successful antitrust lawsuits filed by entrepreneurial medical device makers against GPOs and their dominant supplier partners, independent scholarly research, even a 2009 book, *GROUP PURCHASING ORGANIZATIONS: AN UNDISCLOSED SCANDAL IN THE U. S. HEALTHCARE INDUSTRY* by Distinguished Professor S. Prakash Sethi of the City University of New York.

The money involved is staggering. Three giant purchasing cartels (down from five in early 2020)—Vizient, Premier Inc., and HealthTrust--- control contracting for most of the estimated $300 billion-plus in drugs, devices, and supplies purchased through GPO contracts by 5,000 hospitals and thousands more outpatient clients and nursing homes. All of them are for-profit; Premier Inc. is publicly-held.

Likewise, three huge PBMs—-Express Scripts, CVS Caremark, and OptumRx—- whose total 2017 revenue was about $350 billion, account for about 80% of all outpatient prescriptions. It is no coincidence that most of the drugs in short supply are sold to healthcare facilities through GPO contracts Epinephrine and naloxone injectors, which are sold largely through PBMs, have also been in short supply and have skyrocketed in price because of the same anticompetitive practices. Today, GPOs and PBMs exist for one reason and one reason only:to enrich GPO, PBM and hospital executives and shareholders. Under this system, the rich get richer and the sick get sicker.

GPOs and PBMs are first cousins, joined at the hip by the safe harbor. Whereas GPOs contract for the sale of drugs, devices and supplies to hospitals, outpatient clinics, nursing homes and other institutions, PBMs distribute prescription drugs to individuals through insurance, employer and government plans, Group purchasing cartels literally sell market share to drug makers and other suppliers in the form of sole-source contracts, causing artificial shortages of drugs and inflated prices of those drugs and other supplies. Similarly, drug makers are forced to pay exorbitant kickbacks to the PBMs to get access to their formularies. PBM kickbacks are often called rebates, but they are still kickbacks. They are used to restrict competition, thereby inflating prices to individuals, institutions and taxpayers.

These pernicious practices undermine competition and all but assure that only dominant manufacturers are able to supply lifesavings drugs and devices, making them inaccessible to millions of patients.

GPO anticompetitive practices include, but are not limited to:

- Exclusionary, sole-source, long-term contracts awarded to vendors in return for huge but undisclosed administrative, marketing, advance and other fees (a/k/a kickbacks) as well as prebates and rebates;

- Tying and bundling of product lines to give the advantage to large incumbent suppliers and discourage competition from smaller, entrepreneurial companies with fewer products;

- Forced compliance programs that impose stiff penalties on hospitals and wholesalers if the volume of their purchases from manufacturers on contract drops below 95%, in many cases, for a particular product or product line;

- A Byzantine system of manufacturers' rebates to large, favored distributors that ensures that only those distributors can sell to GPO-member hospitals.

This evidence shows that these abuses gave rise to a corrupt system that:

1) **Undermined innovation and competition** in the entire healthcare supplies marketplace, blocking safer, better and cheaper medical devices and supplies from use in healthcare facilities. We cannot even begin to quantify the human and financial toll when entrepreneurs and inventors decide to forego developing and investing in innovative healthcare products because of the insurmountable barriers to market entry created by this anticompetitive system.

2) **Decimated domestic generic drug production** (and thousands of American jobs), resulting in chronic shortages of hundreds of lifesaving generic drugs, thereby forcing the FDA to allow "temporary" imports, including sterile saline, from several countries and chemotherapeutic agents from a contaminated plant in China. The exorbitant but undisclosed kickbacks extorted by from generic drugmakers and other suppliers have made it unprofitable for many of them continue making these drugs, or forced them to produce them offshore. The increased dependence on China for active pharmaceutical ingredients (APIs) has created potential national security risks. These same abuses contributed in a major way to shortages of

masks and other personal protection equipment (PPE) ---and likely ventilators and other lifesaving equipment.

GPOs are also implicated in at least two other public health crises that occurred years before COVID, notably the deadly 2012 fungal meningitis and 2008 heparin contamination scandals.

3) **Inflated annual healthcare drug and supply costs by 25% to 39%,** or more, or an estimated $100 billion for hospital drugs, devices, and supplies, and another $130 billion for drugs sold to consumers though PBMs. For documentation, see my "White Paper: A Cost Analysis of the 1987 Medicare Anti-kickback Safe Harbor for Group Purchasing Organizations and Pharmacy Benefit Managers" (Updated February 16, 2021, attached).

4) **Purchasing agents, not physicians,** often decide which hip implants, pacemakers, syringes, and other devices are used for patients and by healthcare workers. These decisions are based largely on how much kickback revenue these products can generate for the GPOs and their hospital shareholders, not what is best for patients.

In 2005, then-Senators Herb Kohl (D-WI) and Mike DeWine (R-OH), who presided over four Senate Antitrust hearings on harmful GPO practices, drafted a bipartisan bill that would have repealed the safe harbor. But the "Ensuring Competition in Hospital Purchasing Act" never made it out of the Subcommittee:https://nebula.wsimg.com/a862289b485f16554cf-b4f8d8567221a?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1. Tragically, the bill was killed by the powerful GPO lobby, which includes the American Hospital Association. That was years before drug and PPE shortages appeared on the national radar screen. We believe that if it had been enacted in 2005, there would never have been a drug or PPE shortage crisis. Patients, clinicians, and taxpayers have suffered the consequences, now more than ever.

This travesty persists because of the enormous lobbying and financial clout of these buying cartels and their big hospital owners, whose top officials often receive "sharebacks" (aka "a partial refund of a deliberate overcharge")

from their GPOs. Sharebacks are the glue that holds this entire scam together.

Besides blocking repeal of the safe harbor, this lobby also makes sure there is no disclosure, transparency, regulation or oversight of this industry. Few, if any, outsiders know where all the billions in kickbacks are going. The contracts and fees negotiated between and among GPOs, vendors, distributors, and GPO member hospitals are closely-guarded secrets.This industry spends millions on lobbyists and flacks to disseminate their lies and disinformation:https://www.jdsupra.com/legalnews/hgpii-reports-on-gpo-s-role-in-saving-1698101/.

The perverse incentives created by the ill-conceived safe harbor legislation were enabled by virtually non-existent regulation and oversight by HHS-OIG and other federal agencies, including the Federal Trade Commission and the Department of Justice Antitrust Division, to wit:

- In a July 17, 2000 "advisory opinion," HHS-OIG opined that "advance payments" by sellers to purchasers (GPOs) "… appear to pose a significant risk of fraud and abuse." If HHS OIG had actually taken decisive action to halt these practices, rather than simply issuing opinion letters, global drug and supply shortages may never have happened.

- In April 2003, HHS-OIG published a compliance advisory that quietly extended GPO safe harbor protection to PBM rebates, giving rise to the unceasing upward spiral in the prices of drugs sold through these middlemen. Incredibly, this occurred at a time when the GPO anti-kickback safe harbor was under intense scrutiny by the Senate Antitrust Subcommittee, other federal and state agencies, and national media;

- In September 2010, a Senate Finance Committee report concluded that there was absolutely no independent empirical evidence that GPOs saved hospitals any money at all. Nothing has changed. One would have thought that HHS-OIG might have requested a comprehensive study to determine, once and for all, the cost of the safe harbor. In fact, the GPO industry has insinuated its executives into the federal healthcare bureaucracy to make sure that such a study was never undertaken.

- A March 31, 2012 report by the Government Accountability Office entitled "Group Purchasing Organizations: Federal Oversight and Self-Regulation," called into question HHS-OIG's diligence and effectiveness in overseeing this industry. The GAO wrote that "... since 2004, the office has not routinely exercised its authority to request and review disclosures related to GPO contract administrative fees," adding that "Officials told us that HHS-OIG has not imposed administrative penalties on any GPOs since 2004." It is simply outrageous that a $300 billion+ industry that affects the health, finances, and well-being of every American should be permitted to supervise and regulate itself.

- In November 2012, at our urging, then-Congressman Edward Markey's healthcare staff requested a GAO investigation into the role of GPOs in causing the shortages, the deadly fungal meningitis outbreak, and in inflating supply costs. It was signed by six senior members of Congress, including Mr. Markey. In April 2013, we met with the GAO's healthcare staff, and for the next 18 months provided them with documents in support of the investigation. But the report that was finally issued in November 2014 included virtually nothing about drug shortages. The GPOs had derailed the investigation. On May 7, 2015, I filed a civilian criminal complaint with the Department of Justice, [attached], charging that the Healthcare Supply Chain Association, the GPO trade group, and its CEO, Curtis Rooney, had violated federal obstruction of justice (administrative proceedings) statutes. I have no idea what, if any, action DOJ ever took on my complaint. However, about two months later Mr. Rooney resigned suddenly and without explanation. [See *Modern Healthcare* of July 13, 2015.]

- In 2013, the HHS-OIG inexplicably permitted Premier Inc., one of the two largest GPOs, to go public in a $760 million offering, even after it had stated in an advisory opinion (13-09) on July 16 that the stock sale "could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions." That, HHS-OIG added, could also lead to criminal charges, which in turn could "lead to automatic exclusion from federal healthcare programs." [See *Modern Healthcare* of July 19, 2013].

Less than four months before the HHS-OIG issued its opinion, the Healthcare Supply Chain Association published a paper entitled ”Activities and Perspectives of the Office of Inspector General in the U.S. Department of Health and Human Services Regarding Group Purchasing Organizations (GPOs),” which vigorously supported the legality of the safe harbor. HSCA had hired none other than former HHSIG Richard Kusserow. [attached] to produce it.

It was no coincidence that Kusserow was HHSIG when the safe harbor was enacted and promoted its passage. According to the transcript of the Senate Antitrust Subcommittee hearing of April 30, 2002 (p.14), Kusserow stated on April 17, 1985: “We [HHS OIG] believe the current practice of reimbursement by vendors to group purchasing agents should be permitted… The use of volume purchasing through group purchasing agents clearly reduces the cost of purchases by hospitals. Therefore, we would encourage use of such arrangements regardless of the reimbursement methodology.” His preposterous suggestion that reimbursement methodology was irrelevant demonstrated an abysmal lack of understanding of basic economics, finance and human behavior. Indeed, there is no independent evidence, not then nor 35 years later, that the “safe harbor” model saves hospitals a dime, and a vast amount of empirical and anecdotal evidence that it does exactly the opposite. The only “studies” that the GPO industry is able to cite to support its claims that it saves hospitals money are bogus “sponsored research studies” by ethically-challenged academics, consultants and lawyers on the GPO industry payroll. After Mr. Kusserow left office, he established a consulting firm. The GPO trade group was, and may still be, one of his clients.

By going public, Premier Inc. [PINC] added yet another conflict of interest to the many that were already embedded its business model. Besides being paid by vendors, Premier became beholden to shareholders, notably its hospital owners, and Wall Street. It is difficult to envision how Premier could possibly save money for hospitals while seeking to maximize earnings and shareholder value. The only people who benefit from the “pay-to-play” model are GPO and hospital executives, as indicated in *Modern Healthcare* of November 15, 2014, “Hospitals Cash in Premier Shares.” For the names of Premier shareholder hospitals, see p.15-16, Premier Inc. SEC form S-3 filed Nov. 12, 2014, attached. In our healthcare system today, the

GPO and PBM middlemen are the big winners. Patients and practitioners are the big losers. Indeed, many have even lost their lives.

A July 22, 2013 article on Premier's IPO plan in now-defunct HCMatters.com, a GPO industry mouthpiece, acknowledged that "As a member-driven enterprise, it is common knowledge that Premier and other GPOs "share back" with their members and owners. In fact, many hospital executives who are part of the Premier alliance have learned to rely on that share back as an integral part of their annual compensation":https://nebula.wsimg.com/09cac886d7a44b22d0e78cef17f1c4ee?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

Since then, we have found documents showing that these "sharebacks" or distributions have amounted to $1 million+ to $7 million+ annually per person.

For example, documents filed with the IRS (IRS990s) by the Greater New York Hospital Association (GNYHA) , which is the largest single owner of publicly-held Premier Inc. and until early 2020, a GPO in its own right, show that CEO Kenneth Raske and EVP Lee Perlman each received "equity distributions" from a GNYHA unit of more than $24 million for the four years ending in 2018. This is in addition to their base compensation, which is reportedly among the highest for officials of any U. S. hospital or health care trade group. Under the terms of the Premier IPO, hospital shareholders could cash in tranches amounting to one seventh of their shares each year. The "equity distributions" to Messrs. Raske and Perlman appear to represent the portion they claimed for themselves. Higher prices for hospital goods and shortages translate into millions in their pockets. The Greater New York Hospital Association never responded to my multiple attempts to offer them a opportunity to comment. We do not have the resources to determine the disposition of stock sales of other Premier shareholder facilities. But HHS-OIG does.

We have also obtained a disclosure filing (see below) with a Maryland state agency showing that Kevin Sowers, CEO of Johns Hopkins Health System, who is also a member of Vizient's board of directors, received payment(s) from Vizient of more than $1 million for the 12 months ending June 30, 2019.

To confirm that the payment was actually made by Vizient to Mr. Sowers, I contacted Ms. Angie Bolivar, Vizient's VP for public relations. Her email response appears below. In a follow-up email, I asked, "If the payment was not made to him in his personal capacity, in what capacity was it made?" She never responded. I also contacted Mr. Sowers and Johns Hopkins's PR department, but they never responded with an explanation for the payment.

Begin forwarded message:
From: "Boliver,Angie" <angie.boliver@vizientinc.com>
Subject: RE: Vizient payment of $1,004,231
Date: March 17, 2020 at 5:07:26 PM EDT
To: Phillip Zweig <plzweig@aol.com>

Hi Phil,
We've looked into your inquiry. The payment was not made to Mr. Sowers, who sits on our Board of Directors, in his personal capacity. In fact, Mr. Sowers gets no payments from us for serving on our Board, or otherwise, other than nominal expense reimbursement for travel to Board meetings.
Thanks,
Angie

Angie Boliver
VP, Strategic Communications & Public Relations

We discovered this questionable payment only because Maryland has a law requiring disclosure by hospital executives of such payments. However, it suggests that, at the very least, CEOs of major Vizient shareholder facilities who are also Vizient directors may also receive such payments. Here again, we do not have the resources to investigate that. But a good place to start would be Vizient's board of directors: https://www.vizientinc.com/about-us/governance.

This may explain why two federal government studies, the first by the HHS Inspector General in 2005 and the other by the GAO in 2014 found that GPO shareholder facilities often failed to report GPO distributions (aka sharebacks) to Medicare as required by law.

Eliminate the kickbacks, bribes, sharebacks, sole source contracting and other anticompetitive GPO and PBM practices and the age-old law of supply and demand would kick in again. This broken market would return to normal. Reform of this corrupt marketplace is a quarter-century overdue.

Part III Supplemental Information

Provide the information, explanation, or descriptions required for Part I, lines 1a, 1b, 3, 4a, 4b, 4c, 5a, 5b, 6a, 6b, 7, and 8, and for Part II. Also complete this part for any additional information.

Return Reference	Explanation
SCHEDULE J, Part I	PART I, LINE 1: THE PRESIDENT, TRAVELING FREQUENTLY FOR COMPANY BUSINESS, IS PERMITTED TO USE COMMERCIAL FIRST CLASS TRAVEL (I.E. SEATS IN THE FIRST CLASS CABIN OR A TRAIN OR AIRPLANE) AND DOES SO ON OCCASION. ALL SUCH TRAVEL IS CONSIDERED A BUSINESS EXPENSE AND THEREFORE NOT REPORTED ON FORM W-2. THESE EXPENSES ARE PAID BY THE COMPANY'S BUSINESS CREDIT CARD THAT IS ISSUED TO THE PRESIDENT. ADDITIONALLY, ON OCCASSION, THE PRESIDENT'S SPOUSE MAY ACCOMPANY HIM ON BUSINESS TRIPS. RELEVANT AMOUNTS ARE REPORTED AS TAXABLE INCOME TO THE PRESIDENT. TWO OFFICERS HAVE A CAR AND DRIVER AT THEIR DISPOSAL. THE OFFICERS PAY TAXES ON THEIR IMPUTED VALUE OF THE PERSONAL USE. PART I, LINE 3: GREATER NEW YORK HOSPITAL ASSOCIATION, INC. USED THE FOLLOWING METHODS TO ESTABLISH THE COMPENSATION FOR TOP MANAGEMENT OFFICIALS OF THE ORGANIZATION: COMPENSATION COMMITTEE INDEPENDENT COMPENSATION CONSULTANT FORM 990 OF OTHER ORGANIZATIONS COMPENSATION SURVEY OR STUDY APPROVAL BY THE BOARD OR COMPENSATION COMMITTEE PAYMENT OF COMPENSATION ON SCHEDULE J PAYMENT OF OFFICER'S COMPENSATION AND BENEFITS REPORTED ON SCHEDULE J, PART II IS PAID BY A RELATED ORGANIZATION, GNYHA MANAGEMENT CORPORATION. PART I, LINE 4B: SUPPLEMENTAL NONQUALIFIED RETIREMENT PLAN KENNETH E. RASKE, LEE PERLMAN, DAVID C. RICH, SUSAN C. WALTMAN AND KAREN S. HELLER PARTICIPATE IN ONE OR MORE SUPPLEMENTAL NONQUALIFIED DEFERRED COMPENSATION ARRANGEMENTS THROUGH GNYHA MANAGEMENT CORPORATION, AN ENTITY TAXED AS A CORPORATION. PART I, LINE 4C: EQUITY-BASED COMPENSATION ARRANGEMENT KENNETH E. RASKE, LEE PERLMAN, AND KAREN S. HELLER PARTICIPATED IN AND RECEIVED PAYMENTS FROM AN EQUITY-BASED COMPENSATION ARRANGEMENT SPONSORED BY GNYHA HOLDINGS, LLC (THE "LLC"), A RELATED FOR-PROFIT ORGANIZATION OF GNHYA THAT IS TAXED AS A PARTNERSHIP FOR FEDERAL INCOME TAX PURPOSES. IN THE TAX YEAR 2013, THE LLC GRANTED CERTAIN EQUITY-BASED INTERESTS, SUBJECT TO VESTING, TO CERTAIN INDIVIDUALS IN EXCHANGE FOR THEIR AGREEMENT TO PROVIDE SUBSTANTIAL SERVICES TO THE LLC. UNDER THE TERMS OF THE LLC'S OPERATING AGREEMENT, THE LLC IS PERMITTED TO MAKE DISTRIBUTION PAYMENTS TO INDIVIDUALS OWNING SUCH EQUITY-BASED INTERESTS. AT THE TIME OF ISSUANCE, THE EQUITY-BASED INTERESTS GRANTS TO THE INDIVIDUALS NAMED BELOW HAD A FAIR MARKET VALUE OF ZERO PURSUANT TO ELECTIONS MADE UNDER SECTION 83(B). THE DISTRIBUTION PAYMENTS FROM THE EQUITY-BASED COMPENSATION ARRANGEMENTS FOR TAX YEAR 2016 ARE AS FOLLOWS: KENNETH E. RASKE $11,186,389; LEE PERLMAN $11,667,931; AND KAREN S. HELLER $777,862.
SCHEDULE J, PART II	THE GREATER NEW YORK HOSPITAL ASSOCIATION (GNYHA) IS A 501(C)(6) ORGANIZATION THAT PROVIDES ADVOCACY SERVICES FOR ITS MEMBER HOSPITALS TO ASSIST THEM IN IMPROVING ACCESS TO AND THE QUALITY AND COST OF HEALTH CARE. THESE SERVICES INCLUDE ADVOCACY SERVICES AT THE NATIONAL LEVEL FOR ITS NEW YORK, NEW JERSEY, CONNECTICUT, AND RHODE ISLAND HOSPITAL MEMBERS AND ADVOCACY SERVICES AT THE STATE LEVEL FOR ITS New York HOSPITAL AND HEALTH SYSTEM MEMBERS. GNYHA'S RELATED ENTITIES INCLUDE FIVE FOR-PROFIT COMPANIES THAT PROVIDE GROUP PURCHASING, SUPPLY CHAIN AND OTHER CONSULTING, AND OTHER SERVICES TO A WIDE ARRAY OF CUSTOMERS, INCLUDING ACUTE AND NON-ACUTE CARE HEALTH CARE PROVIDERS FOR THE PURPOSES OF HELPING THEM ACHIEVE THEIR MISSIONS. THESE COMPANIES FOCUS PRIMARILY ON HELPING HEALTH CARE ORGANIZATIONS REDUCE THEIR COSTS AND OPERATE MORE EFFICIENTLY. GNYHA'S RELATED ENTITIES ALSO INCLUDE A 501(C)(3) FOUNDATION, WHICH FILES A SEPARATE FORM 990.

Part III Supplemental Information

Provide the information, explanation, or descriptions required for Part I, lines 1a, 1b, 3, 4a, 4b, 4c, 5a, 5b, 6a, 6b, 7, and 8, and for Part II. Also complete this part for any additional information.

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SCHEDULE J, PART II	THE GREATER NEW YORK HOSPITAL ASSOCIATION (GNYHA) IS A 501(C)(6) ORGANIZATION THAT PROVIDES ADVOCACY SERVICES FOR ITS MEMBER HOSPITALS TO ASSIST THEM IN IMPROVING ACCESS TO AND THE QUALITY AND COST OF HEALTH CARE THESE SERVICES INCLUDE ADVOCACY SERVICES AT THE NATIONAL LEVEL FOR ITS NEW YORK, NEW JERSEY, CONNECTICUT, AND RHODE ISLAND HOSPITAL MEMBERS AND ADVOCACY SERVICES AT THE STATE LEVEL FOR ITS NEW YORK HOSPITAL MEMBERS GNYHA'S RELATED ENTITIES INCLUDE FIVE FOR-PROFIT COMPANIES THAT PROVIDE GROUP PURCHASING, SUPPLY CHAIN CONSULTING, AND OTHER SERVICES TO A WIDE ARRAY OF CUSTOMERS, INCLUDING ACUTE AND NON-ACUTE CARE HEALTH CARE PROVIDERS FOR THE PURPOSES OF HELPING THEM ACHIEVE THEIR MISSIONS THESE COMPANIES FOCUS PRIMARILY ON HELPING HEALTH CARE ORGANIZATIONS REDUCE THEIR COSTS AND OPERATE MORE EFFICIENTLY GNYHA'S RELATED ENTITIES ALSO INCLUDE A 501(C) (3) FOUNDATION, WHICH FILES A SEPARATE FORM 990 SCHEDULE J, PART II, COLUMN B (II) KENNETH E RASKE AND LEE PERLMAN PARTICIPATED IN THE THREE-YEAR CYCLE LONG-TERM INCENTIVE COMPENSATION (LTIC) PLANS FOR GNYHA MANAGEMENT CORPORATION AND SUBSIDIARIES - GNYHA'S FOR-PROFIT ENTITIES FINAL LTIC PAYOUTS WERE MADE IN 2015 $618.030 WAS PAID TO MR RASKE AND $706.800 TO MR PERLMAN

Schedule J (Form 990) 2017 Page **3**

Part III Supplemental Information

Provide the information, explanation, or descriptions required for Part I, lines 1a, 1b, 3, 4a, 4b, 4c, 5a, 5b, 6a, 6b, 7, and 8, and for Part II Also complete this part for any additional information

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Schedule J (Form 990) 2018 Page **3**

Part III Supplemental Information

Provide the information, explanation, or descriptions required for Part I, lines 1a, 1b, 3, 4a, 4b, 4c, 5a, 5b, 6a, 6b, 7, and 8, and for Part II. Also complete this part for any additional information.

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hscrc.trustees@maryland.gov <hscrc.trustees@maryland.gov> Reply-To: hscrc.trustees@maryland.gov
To: hscrc.trustees@maryland.gov

DATE OF STATEMENT: 9/30/2019

PERIOD COVERED: FROM: 07/01/2018 **TO:** 06/30/2019

TRUSTEE, DIRECTOR, OR OFFICER NAME: Kevin Sowers, M.S.N., R.N., F.A.A.N.

Mon, Sep 30, 2019 at 11:11 AM

HSCRC Trustees -MDH- <hscrc.trustees@maryland.gov>

TRUSTEE, DIRECTOR, OR OFFICER BUSINESS ADDRESS: 600 North Wolfe St., Baltimore, MD 21287

HOSPITAL NAME: Johns Hopkins Hospital

HOSPITAL ADDRESS: 600 North Wolfe St., Baltimore, MD 21287

TRUSTEE, DIRECTOR, OR OFFICER'S BUSINESS ENTITY NAME: Vizient, Inc.

TRUSTEE, DIRECTOR, OR OFFICER'S BUSINESS ENTITY ADDRESS: 290 E. John Carpenter Freeway, Irving, TX 75062

MAJOR BUSINESS, PROFESSIONAL, OR ACADEMIC ACTIVITY OF TRUSTEE, DIRECTOR, OR OFFICER'S BUSINESS ENTITY: Health care

TITLE, RELATIONSHIP, OR POSITION OF TRUSTEE, DIRECTOR, OR OFFICER IN THE BUSINESS ENTITY: Board member

TYPE OR NATURE OF BUSINESS TRANSACTIONS, DEALINGS, OR SERVICES BY AND BETWEEN THE HOSPITAL TRUSTEE, DIRECTOR, OR OFFICER'S BUSINESS ENTITY HAVING AN ACTUAL OR IMPUTED VALUE OR WORTH OF $10,000 OR MORE TO THE TRUSTEE, DIRECTOR, OR OFFICER'S BUSINESS ENTITY: Hospital and healthcare services

MONETARY VALUE OF THE BUSINESS TRANSACTION(S)TO THE TRUSTEE, DIRECTOR, OR OFFICER'S BUSINESS ENTITY: $1,004,231.00

DECLARATION OF TRUSTEE, DIRECTOR, OR OFFICER THAT THE STATEMENT IS TRUE TO THE BEST OF HIS/HER KNOWLEDGE, INFORMATION, AND BELIEF THAT THIS STATEMENT IS TRUE AND CORRECT UNDER PENALTIES OF PERJURY:

PRINTED NAME OF TRUSTEE, DIRECTOR, OR OFFICER: Kevin Sowers **COMPLETED BY:** Jenna Moore, jmoor159@jhmi.edu, 4109556061

Note: A schematic diagram of the GPO system is attached to my submission.

Part II: Impact of the GPO/PBM Safe Harbor: Artificial Drug and PPE Shortages

These same anticompetitive practices—long-term, sole-source contracts, tying and bundling, penalty pricing, and more--- have caused chronic artificial shortages and skyrocketing prices of hundreds of lifesaving generic drugs, which are generally administered in hospitals, outpatient facilities and clinics. These shortages began appearing in the late 1990s and early 2000s, and started making headlines in 2010-2011. Millions of patients continue to suffer needlessly because of these shortages. Many have also

died. Not surprisingly, COVID-19 has exacerbated shortages of many these drugs.

The seeds for this catastrophic market failure were arguably planted in the mid-1990s when Premier co-founded, on a $100 investment, American Pharmaceutical Partners. Its purpose: to take control of the hospital generic drug marketplace and enrich Premier executives by taking it public in late 2001. For the full story, see *The New York Times* of March 26, 2002, "When a Buyer for Hospitals has a Stake in Drugs it Buys."

The independent documentation on the role of GPOs in causing the global drug shortage crisis is overwhelming. It includes:

- An American Antitrust Institute white paper of May 2012
- The House Oversight and Reform report of June 15, 2012
- The Government Accountability Office report of February 2014, which was mandated by Congress
- Testimony in least three congressional hearings: the House Energy and Commerce Committee hearing of September 23, 2011 and Senate HELP hearing of December 15, 2011, and the House Energy and Commerce Committee hearing of February 10, 2014.
- And much more.

More recently, the FDA drug shortage report of October 29, 2019 (updated Feb. 21, 2020), while seriously flawed in many respects, pointed to GPOs as a key contributor. It concluded that "the economic forces driving drug shortages arise primarily from private sector behavior, including business decisions made by pharmaceutical firms, GPOs and other intermediaries in the supply chain, as well as drug purchasers such as hospitals and other health care providers." See https://www.fda.gov/media/131130/download.

When the FDA published its report, it had actually known about the role of GPOs in causing the shortages for at least eight years but had scrupulously avoided any reference to them, for reasons we can only speculate on. Strangely, the report failed to mention testimony of HHS Assistant Secretary Howard K. Koh before the House Energy and Commerce Committee hearing of September 23, 2011. He was accompanied by FDA Deputy Director Sandra Kweder M.D.:

P. 47.
Mr. Shimkus (R-IL). “What has distorted the fundamental principle of supply and demand…I think that is the heart of the issue.”

Mr. Koh. “…First of all, these agreements are made often through these long-term contracts and so also this whole process involves multiple stakeholders, especially and including the pharmacy benefit managers and the group purchasing organizations. So it complicates this environment and sort of does make relevant the sort of standard supply and demand economic principles that we see in other businesses.”

Mr. Ptts (R-PA) “Dr. Kweder?”
Ms. Kweder. “You have said what I would say. Thank you.”

Page 60.

Mr. Gingrey (R-GA). “It would seem because of supply and demand that the company would be able to raises their prices. Are there any government rules, regulations, laws, pharmacy benefit managers that would cause them not to be able to raise their prices even though the market would certain let them do that otherwise?”

Mr. Koh. “Yes, Congressman, so we have come to understand that this is a complex business situation where the standard economic principles of supply and demand do not easily apply. And we have manufacturers, we have purchasers, providers, hospitals, we have group purchasing organizations and pharmacy benefit managers, so we have multiple forces here all working to the final outcome that ordinarily you would see with a rise in pricing profit, but that doesn’t apply here.”

For more detail and documentation on how GPOs and PBMs caused drug shortages, see the attached comments I previously submitted to the FDA in response to its request for comment on the root causes of drug shortages:https://www.regulations.gov/document?D=FDA-2018-N-3272-0215.

For its part, the GPO industry and its proxies have persistently disseminated the canard that the causes of the shortages are “complex and multifactorial.” Over the years, they’ve offered up a series of explanations, all of which have been thoroughly discredited. These include changes in the formula for Medicare reimbursement of drugs; alleged price-gouging by so-called “grey market” distributors; a backlog in FDA applications, and on and on. No mention, of course, of their exhaustively documented anticompetitive abuses.

For an overview of GPOs and their role in causing drug shortages:

- Chapter excerpt on GPOs in MONOPOLIZED, published July 21, 2020 by David Dayen, executive editor of the *American Prospect*:https://prospect.org/culture/books/monopolies-are-why-salt-and-water-in-a-bag-became-scarce-dayen-monopolized-book/.

- Journal of the American Medical Association of Nov. 13, 2018, "Group Purchasing Organizations, Healthcare Costs, and Drug Shortages" by Marty Makary M.D. M.P.H. of Johns Hopkins. Dr. Makary also devotes part of a chapter to the GPO issue in his highly acclaimed 2019 book, *THE PRICE WE PAY.*

- *Wall Street Journal* oped of May 8, 2018, "Where Does the Law Against Kickbacks Not Apply? Your Hospital": https://nebula.wsimg.com/fe4916f65b3cd1d2e8052ee95960260a?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

- *New York Times* op-ed of Sept. 3, 2013, "How a Cabal Keeps Generics Scarce": https://www.nytimes.com/2013/09/03/opinion/how-a-cabal-keeps-generics-scarce.html?module=Search&mabReward=relbias%3Ar%2C%7B%221%22%3A%22RI%3A6%22%7D.

Many other articles are posted on the "Media Reports" page of our website.

After reviewing the documentation on the role of GPOs in causing drug shortages, it should not be a stretch to conclude that the same anticompetitive GPO practices have also contributed mightily to the scarcity of masks and other personal protection equipment (PPE) as well as ventilators and other supplies during the pandemic. GPOs contract for all of these goods, in the same way they contract for drugs used in hospitals and other facilities.

To be sure, the demand for these goods has surged as a result of the pandemic. But to the extent that supplies have been depleted because of the

monopolistic practices enumerated herein, the GPO industry and their hospital owners must be held accountable.

Unfortunately, the April 2020 HHS-OIG report "Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020" did not delve into the underlying cause of the shortages of PPE and other supplies. It stated only that "Hospitals pointed to the lack of a robust supply chain as delaying or preventing them from restocking the PPE needed to protect staff." That was a gross understatement. Virtually every player in the supply chain, from mid-level supervisor to C-Suite executive, is well aware of the anticompetitive practices of GPOs. But they're afraid to criticize these cartels publicly for fear of retribution.

The underlying cause of the surgical mask shortages was revealed in a simple Google search. In an August 14, 2017 piece on the difficulties faced by Texas-based Prestige Ameritech, one of a handful of domestic mask manufacturers, the *Dallas Morning News* wrote: "Small companies like Prestige Ameritech say they are routinely shut out of sales to hospitals and health systems, as large competitors secure the exclusive contracts with purchasing groups":https://nebula.wsimg.com/5f985f2f2b9881e1c42e0b010d62befc?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1. They're locked out of the hospital.

Alerted to the earlier article, the *Dallas Morning News* of April 17, 2020 published a scathing report, focusing on Vizient, on how exclusionary GPO pricing and contracting practices caused mask shortages:https://www.dallasnews.com/news/public-health/2020/04/17/heres-one-reason-medical-costs-are-high-we-have-shortages-and-made-in-america-isnt-working/. The GPO industry couldn't afford to have Prestige Ameritech CEO Mike Bowen bashing GPOs in the midst of a global pandemic. So in late May, Premier announced that it had acquired a minority stake in the company.

Lack of competition results not only in higher prices, but also inferior goods. Consider the case of Halyard Health, which was accused in a 2016 class-action lawsuit of making defective surgical gowns that leaked during the 2014 Ebola epidemic. A year earlier, Premier Inc. had awarded Halyard Health its "Supplier Legacy Award for Operational Excellence" . *60 Minutes* later aired a scathing segment on the episode.

History repeated itself in January 2020 when Cardinal Health, one of the "Big Three" GPO-authorized distributors, was forced to recall millions of contaminated surgical gowns. See *Modern Healthcare* of January 24, 2020:https://www.modernhealthcare.com/safety-quality/gown-recall-entangles-healthcare-supply-chain. Coming just before the pandemic began to spread across the planet, the timing could not have been worse. It surely contributed to the shortage of hospital gowns that was to come.

Testimony before the Senate Antitrust Subcommittee hearing of April 30, 2002 strongly suggests that anticompetitive GPO abuses be responsible for the shortages of ventilators needed to treat severely ill COVID patients. Passionately asking "What is the cost of a dead baby?", California neonatologist Mitchell Goldstein M.D., bluntly described how GPOs harmed patients by blocking entrepreneurial device makers from marketing innovative pulse oximeters and ventilators to hospitals. Statement by Mitchell Goldstein MD. [Dr. Goldstein is now chair of PADS.]

GPOs may have also played a role in causing the shortages of swabs and reagents for COVID testing. This requires more investigation.

But perhaps the most compelling indictment of GPOs came from an unlikely source: John Strong, for years a stalwart defender of GPOs as CEO of a small GPO and later as a senior Premier executive. In a surprising Linkedin post of May 2020 entitled "How sole source captured my soul…and blew my response to the pandemic," he wrote, "Looking back 40 years, our healthcare supply chain was arguably better prepared for a pandemic because many buyers had dual suppliers of many items-with more inventory resting on more shelves.":https://www.linkedin.com/posts/access-strategy-partners-inc_sole-sourcing-role-in-post-pandemic-activity-6667118204176924672-_KF5/.

Part III: Cost of the Safe Harbor

Industry lobbyists have also blocked attempts by federal agencies to study the cost of the safe harbor, as I documented in my May 7, 2015 complaint to the Public Integrity unit, U. S. Justice Department, Southern District.

Lacking access to secret GPO contracts and pricing data, I examined publicly available empirical and anecdotal documentation on hospital supply pricing dating back to the late 1990s. I concluded that GPO kickbacks/sharebacks have inflated drug/device/supply prices by at least 30%, or roughly $100 billion annually, and drove up prices of drugs sold to individuals through PBMs by another $130 billion, for a total of about $230 billion.

A antitrust class action lawsuit winding its way through federal court in Illinois supports my conclusion about the inflationary impact of the GPO safe harbor. In Marion Healthcare *et al* vs. Becton Dickinson (BD) *et al*, two small healthcare providers allege that defendants BD, Cardinal and McKesson conspired with Vizient and Premier to inflate prices of syringes and catheters by up to 37%.

In fact, this figure is merely the starting point. In billing patients, insurers, and government payors, hospitals add a multiple (4.5 is said to be a rule of thumb) of the vendor invoice price. [For more on that, see "Medical Monopoly," the cover story in dBusiness of Nov/Dec. 2018].

I submitted my Safe Harbor Cost Analysis to HHSIG in response to its request for comment on its proposal to rescind the safe harbor for pharmacy benefit manager (PBM) rebates (kickbacks). An updated version of that analysis, including more detail on Marion Healthcare, is attached as part of this submission.

Part IV: PBM Safe Harbor

In his 2019 proposal to rescind the safe harbor for PBM rebates for Medicare and Medicaid plans, former HHS Secretary Alex Azar acknowledged the role of the safe harbor in inflating drug prices. He went even further, urging Congress to repeal the safe harbor for ALL PBM plans.

In my April 2019 comments to HHSOIG, I endorsed the proposed rule. I'm summarizing those comments here because implementation of the rule has

been delayed. Here's the link to my original comments: https://www.regulations.gov/document?D=HHSIG-2019-0001-19853.

In my comments, I argued that the Congressional Budget Office and two private actuarial firms wrongly concluded that the proposal would increase costs for seniors. In fact, the savings would be significant. That's because the studies by the Congressional Budget Office and the two private actuarial firms that were hired to analyze the cost of the proposal do not appear to have accounted for the anticompetitive impact of rebates (aka kickbacks) on the prices paid by government programs, drug plans, and beneficiaries. In other words, the scenarios reported by the three appear to be based entirely on estimates of the dollar amount of the rebates. They failed to consider the obvious anticompetitive impact on prices of the existing "pay-to-play" system. I actually spoke by phone to an actuary at one of the firms, who explained that they couldn't do that because that were no data.

In other words, the projected single digit monthly increases in insurance premiums for some beneficiaries are a pittance compared with the much larger savings that millions of beneficiaries and federal health care programs would likely realize from enhanced competition. The downside is *de minimus*, whereas the potential upside is huge.

What we do know for certain, after more than two centuries of experience, is that competition lowers prices, whereas cartels inflate them.

The PBMs, like the GPOs, have proven extremely adept at navigating around the safe harbor rules to enrich insiders and shareholders at the expense of patients and taxpayers. Restoring market competition in the PBM supply chain would reduce prices and end the shortages of devices like epinephrine and naloxone injectors, which are sold through PBMs and retail pharmacies.

Parenthetically, for years independent research cited the PBM rebates as the major reason for the surge in PBM drug prices. But to the best of my knowledge, we were the first to connect the dots, in a June 2017 press release (attached), between the GPO safe harbor and the surge in rebates and PBM prices that followed. I have good reason to believe we advanced the ball significantly on this issue. We also cited the connection in our *Wall*

Street Journal oped of May 8, 2018, “Where Does the Law Against Kick-backs Not Apply? Your Hospital.”

Part V: Obstruction of Administrative Proceedings and other Egregious and Potentially Illegal GPO behavior

Besides spending countless millions on lobbyists, PR specialists and campaign contributions to preserve the safe harbor, the GPO industry has engaged in egregious and potential illegal activities to silence critics and buy influential supporters. And in at least one instance, a top GPO contracting officer allegedly demanded sexual favors from a female entrepreneur in return for contracts.

o GPOs or their cohorts have also employed thuggish tactics to try to shut us down. They’ve failed. They even hired a bogus online “investigative” outfit called “Checks and Balances” to try to harass me and individual PADS members who had written articles critical of the industry. They even filed complaints with the presidents of several universities falsely alleging that these physicians had financial conflicts of interest. The universities ultimately took no action, but busy world-class academic physicians wasted many hours dealing with this charade. Rather than subject our physician members to any further stress, I’ll cite as an example their attack on me: https://checksandbalancesproject.org/philip-zweig-disrupts-health-policy-forum/.

o GPO officials and their hospital partners have also threatened several of our physician members and allies with the loss of their jobs for speaking out. Others have been denied promised promotions and research grants. As a result, a few have asked for their names to be deleted from our online roster. Those involved may be willing to corroborate these incidents with you in confidence.

o As previously discussed, GPO industry lobbyists even derailed a GAO study, requested November 15, 2012 by six senior House members, that

would have examined, among other things, the cost of the safe harbor, the role of GPOs in causing the shortages and the deadly 2012 fungal meningitis outbreak.

o The GPOs and their dominant supplier partners have also secured the silence of medical society "stakeholders" and nonprofits with "donations" and "grants"—despite the harm GPO practices have inflicted on rank and file members and their patients. In at least one instance, they have threatened officials of a leading national physicians' society for passing a 2017 resolution calling for repeal of the safe harbor. Although the society did not rescind the resolution, it abandoned plans, as called for in the resolution, to lobby Congress for repeal.

o Incredibly, according to unsolicited emails provided by a female New York-area oncologist on a no-strings-attached basis, a senior GPO executive even demanded sexual favors from her in return for contracts for her boutique prosthetics business. She declined. I would be prepared to provide the emails on request.

Part VI: Recommendations

We have been working for many years to expose the fatal flaws of the unsafe safe harbor statute and to press Congress to repeal it. Repeal would restore competition and integrity to the healthcare supply chain, including the broken drug marketplace.

It would immediately send a signal to established generic drug makers that they would be able to turn a profit even after upgrading plant and equipment to comply with FDA requirements and good manufacturing practice (GMP). Repeal would also encourage new manufacturers to enter the marketplace.

Repeal legislation would in effect reinstate the tried and tested, pre-safe harbor co-op GPO business model, in which GPOs actually saved hospitals money. It is important to note that repeal would by no means eliminate GPOs, only the perverse safe harbor payments model. We have no problem at all with the old, successful co-op model.

We understand, of course, that the Office of Inspector General does not have the authority to repeal the safe harbor. Only Congress does. But since this issue has been before Congress for more than two decades, we know we can't count on Congress, the White House, or any relevant federal agency to take the lead in repealing the safe harbor anytime soon.

For years, members of Congress have kicked the can down the road on shortages with interminable hearings and ineffectual letters (accompanied by press releases) to the FDA, which lacks the power to fix the problem. The latest example: the Senate Finance Committee hearing of July 30, 2020 on the health care supply chain. The lead witness, who was described by Committee Chair Chuck Grassley as a supply chain "expert," was an employee of Vizient, and the second was a supply chain manager at Ohio Health, a Vizient shareholder facility. Not only have the foxes been allowed into the henhouse, but they've been invited to testify as "experts" before a Senate committee.

So we urge your office to explore every possible mechanism for mitigating the harmful impact of the GPO and PBM safe harbors and to consider making the case to Congress for repeal.

More specifically, we believe that there are modifications in the safe harbor rules that OIG can make that would mitigate the harmful human and financial impact of the GPO industry:

o Fee Structure. The existing rules, as I understand them, call for a "soft cap" of 3% on "administrative fees" paid by suppliers to GPOs (or more precisely, extorted by GPOs from suppliers). If they exceed that level, GPOs are supposed to inform their hospitals. Unfortunately, the GPOs have done an end run around the 3% cap on "admin fees" by inventing countless other fees, including conversion, marketing, and "advance" fees---even fees to sit next to a GPO executive at dinner!

Remedy: REQUIRE an all-in 3% hard cap that encompasses **ALL** GPO fees, including any they may add in the future.

WE RECOMMEND A SPECIAL FRAUD ALERT TO ENFORCE THIS PROPOSED NEW RULE

o Lack of Transparency and Disclosure of GPO Kickbacks and Distributions/Sharebacks; Fees; and Contract terms and Pricing. In requiring that GPOs inform its member hospitals of vendor fees that exceed the 3% "soft cap, HHSIG may have assumed that hospital executives cared about excess fees. Rest assured that they do not. That's because higher fees translate into bigger "sharebacks" for themselves personally. Recall that the only data we have on excess vendor fees were obtained in discovery in a federal whistleblower lawsuit against Novation (now Vizient). Those fees sometimes exceeded half of a supplier's total annual revenue for a single drug or other product. To be sure, that information is dated, but that fact itself serves to highlight the total lack of current data on GPO practices.

Further, all of the GPO contracts, including fees, amounts, terms, pricing, and whether they are sole-source, dual source, or multi-source are secret. Besides making sure that Congress never repeals the safe harbor, their well-heeled lobbyists ensure that this information remains a secret as well. As things stand, there is no way to systematically uncover this critical information. Most of it is obtained by chance. For example, in researching the role of GPO contracting in the shortages of IV solutions, I found, after a lengthy Google searc this 2007 Baxter Healthcare press release boasting of its sole source IV contracts:https://nebula.wsimg.com/aaa5dd2ecdbff775fd9a64971fd3469f?AccessKeyId=62BC662C928C06F7384C&disposition=0&alloworigin=1.

Remedy: REQUIRE GPOs and hospitals to report ALL excess fees and details on all supplier contracts to HHS OIG, to be posted on the HHS OIG or CMS website with the names of the GPOs and suppliers.

WE RECOMMEND A SPECIAL FRAUD ALERT TO ENFORCE THIS PROPOSED NEW RULE

o **Failure by many hospital to report sharebacks/rebates received from GPOs to CMS as the law requires,** according to two federal government reports. But to the best of my knowledge, the HHS OIG has never acted on these findings.

Remedy: Enforce the law by REQUIRING hospitals and GPOs to report sharebacks/rebates to HHS OIG for posting on the OIG website. HHS OIG shall impose monetary penalties on GPOs and facilities that fail to do so.

WE RECOMMEND A SPECIAL FRAUD ALERT TO ENFORCE THIS LAW

o **Sole-source and long-term contracts:** GPOs make their money by selling market share via long-term sole-source contracts, undermining competition and inflating prices. Some of these contracts extend up to seven years. These abuses discourage new marketplace entrants and causes existing manufacturers to stop making certain drugs and other items.

Remedy: REQUIRE GPOs to award contracts under an open competitive bid system. Sole-source contracts shall be prohibited unless there are no other qualified bidders and contracts shall be limited to three years. Additionally, HHS OIG shall establish an arbitration process for vendor complaints about GPO contract awards.

WE RECOMMEND A SPECIAL FRAUD ALERT TO ENFORCE THIS PROPOSED NEW RULE

o The documentary evidence shows that executives of GPO shareholder hospitals and association executives are personally receiving millions in distributions and remuneration from GPOs

Remedy: No hospital or association executive or non-public GPO shareholder should personally receive equity distributions, dividends or other payments based on their institutions' GPO shares.

WE RECOMMEND A SPECIAL FRAUD ALERT TO ENFORCE THIS PROPOSED NEW RULE

o **There is absolutely no independent evidence that GPOs save hospitals money on supplies, and overwhelming evidence that they actually inflate supply prices.**

Remedy: HHS OIG should conduct a comprehensive investigation of the impact of GPOs on our health care system, including an audit of all major GPOs and shareholder hospitals to determine 1) the cost of the safe harbor to the healthcare system, federal and state governments, and taxpayers; and 2) how GPOs and their share holder hospitals are using the "fees," and 3) who is actually receiving sharebacks/distributions from the GPOs and how much.

o **Delay in implementation of proposal to rescind PBM safe harbor for Medicare and Medicaid plans.**

Remedy: Urge HHS to push for immediate implementation of the rule to rescind the PBM safe harbor for Medicare and Medicaid programs.

We are confident that this action would break the never-ceasing upward spiral in the prices of drugs sold through PBMs. So we were disappointed that implementation would be delayed for one year. This rule is good policy. We understand the desire by the Biden administration to review all policy initiatives of the previous administration, but we urge the HHS OIG to enable implementation of this consumer-friendly rule to take effect in January 2022, as originally scheduled. Billions are at stake for consumers and taxpayers.

Part VII: Conclusion

The GPO safe harbor was destined for failure as soon as it was enacted. The perverse incentives it created should have been obvious at the outset. Bad policy drove out good. Now, more than 30 years later, it's clear that Congress broke the drug and health care supply marketplace.

Thanks to the safe harbor, the GPOs and PBMs have turned American healthcare into a vestige of the disgraced ex-Soviet economic system. Millions of patients and medical practitioners will continue to be denied access to lifesaving medications and the best, safest, and most cost-effective devices and supplies until full, free and open competition is restored to this dysfunctional marketplace.

Congress enacted this misbegotten statute, and only Congress can repeal it. However, HHS OIG could mitigate the damage by modifying the rules as suggested above. Three decades after the rules were originally implemented, there are still enough loopholes embedded in them to drive a truck through.

In conclusion, we appeal to you in the strongest possible terms to use all the powers vested in your office to halt these illegal practices and restore competition, integrity, and innovation to the American healthcare drug/supply chain.

Feel free to contact me if you wish to discuss this further.

Full disclosure: PADS members, including myself, have no conflicts or financial vested interests in this matter. We are working on this project on a pro bono basis and covering all expenses out of our own pockets.

Respectfully submitted,

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