LOWERING HEALTHCARE COSTS THROUGH SAFE HARBOR REPEAL

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ABSTRACT

The 1987 Medicare Anti-Kickback Safe Harbor statute exempted hospital Group Purchasing Organizations (in-patient side) and later, Pharmacy Benefit Managers (out-patient side), from criminal penalties for taking rebates/kickbacks from suppliers. This law unintentionally created a $600+ billion nationwide distribution monopoly of medical supplies and medications.

While legal, this misguided "Safe Harbor" statute gave rise to an unimaginably corrupt pay-to-play system. This distribution monopoly collects administrative fees, marketing fees, advances, conversion fees, pre-bates, rebates, and "sharebacks" simply to let a given medication or medical device gain access to the healthcare marketplace. These fees add an estimated $200 billion of unnecessary expense to American healthcare every year. In short, the 1987 "Safe Harbor" statute legalizes contracts and payments that in any other industry would be subject to criminal prosecution.

Repeal of the "Safe Harbor" provision would reduce costs of drugs and healthcare supplies by an estimated 30% and save Medicare and Medicaid approximately $75 billion annually. Over time, renewed free market competition would produce additional innovation and further cost reductions.

THE PLAYERS

- **Hospital Group Purchasing Organizations (GPOs)** control the purchase of over $300 billion annually of drugs, devices and supplies for about 5,000 hospitals and thousands more outpatient clinics and alternative care facilities.

  The GPO industry is highly concentrated. According to the Government Accountability Office (GAO), four giant GPOs account for over 90% of total annual GPO contracting volume. In size order, they are:
  1) Vizient Inc.
  2) Premier Inc.
  3) HealthTrust
  4) Intalere

- In 2003, **Pharmacy Benefit Managers (PBMs)** quietly asserted control over outpatient drugs and devices after petitioning HHS OIG to extend the "Safe Harbor Law" to cover the PBM industry. Drug manufacturers compete with each other to get

their products on PBM formularies by paying ever-larger rebates/ kickbacks. They then raise their prices to offset these excess costs.

The PBM industry is highly concentrated as well. Three huge companies control over 80% of the PBM market and more than 70% of all prescriptions dispensed in the United States. In 2016, these three PBMs reported aggregate net revenue of $303.7 billion. In size order, they are:

1) CVS Caremark
2) Express Scripts
3) Optum Rx

- To give a sense of the magnitude and power of this distribution monopoly, in December of 2017, CVS Caremark (the largest PBM) announced its $69 billion purchase of Aetna (the nation's largest health insurer). This is the market equivalent of a trucking company that delivers soft drinks purchasing Coca-Cola or Pepsi.

BACKGROUND

In brief, here is how this system works:

- Long before online ordering and "just-in-time" inventory, the first hospital GPO was founded in New York City in 1910. GPOs were specifically developed to reduce members' supply costs by buying in bulk. Under that cooperative business model, hospitals paid dues to the GPOs to cover administrative expenses. By design, the "bulk savings" outweighed the "administrative" costs.

  That system worked well for about 80 years because GPOs served member hospitals. Payments and incentives aligned with consumer interests.

- That business model changed in 1987 when Congress enacted the anti-kickback "Safe Harbor" provision. GPOs were now exempted from criminal prosecution for taking kickbacks from healthcare suppliers. After the Inspector General of the Department of Health and Human Services implemented the "Safe Harbor" rules in 1991, vendors, not hospitals, paid GPO "administrative" expenses.

  Rather than reducing costs for member hospitals, GPOs could now extract a variety of fees from both suppliers and the medical supply chain for the "privilege" of a given medication or medical device gaining access to the healthcare market. Rather of serving member hospitals by cutting costs, GPOs rapidly became a highly paid middleman.

- While GPO's service the in-patient side, the PBM industry services the out-patient side. PBMs allocate market share and may confer "Preferred Distributor" status to middle market distributors. (Sometimes these distributors are entirely owned by PBM shell corporations.) PBMs use secret contracts to manipulate pricing. Manufacturers

and distributors unwilling or unable to pay the kickbacks are removed from the supply chain.

- Predictably, this gave rise to a pay-to-play system. Suppliers literally buy market share by paying exorbitant fees to the GPOs/PBMs in return for contracts giving their products exclusive access to GPO-member hospitals and PBM preferred distributors.

  This system created supplier monopolies by slashing the number of suppliers of vital generic drugs, devices, and other medical supplies; it also discouraged potential competitors from entering the marketplace. Most importantly, the GPO/PBM cartel is a powerful Buyers' Monopoly, or Monopsony. This is the rarest and most harmful type of monopoly.

- Under this perverse system, purchasing agents, *not clinicians*, typically decide which drugs, medical devices and supplies physicians can use for their patients. These decisions are based largely on how much kickback revenue these products generate for the GPO or PBM, *not what is best for patients*. Patients and healthcare workers are often denied access to lifesaving, cost-effective goods including drugs, hip implants, pacemakers, pulse oximeters, safety needles and countless other products.

- Under the safe harbor rules, "admin" fees were to be limited to 3% of sales. If they exceeded that amount, the GPOs were supposed to report the fees to their member hospitals. The available evidence indicates that total kickbacks paid by suppliers to GPOs/PBMs have often exceeded half of the suppliers' annual revenue for a single drug! Because kickbacks are generated on a percentage of total contract volume (sales), the higher the price of a medication or medical device, the larger the kickback for the GPO/PBM.

- The HHS Inspector General was empowered to request data excess GPO/PBM fees. However, it has often chosen not to do so. In fact, a 2012 GAO investigation—requested by three U.S. Senators—found that the HHS OIG had not exercised its oversight authority in years.

- These anti-competitive contracting and pricing practices, self-dealing, conflicts of interest and other abuses have forced many firms to stop making inexpensive generic drugs rather than produce them at a loss. They've also crippled the ability of other manufacturers to maintain their plants, equipment, and quality control, resulting in tainted drugs, adverse FDA inspections, and plant closings.

- The deadly 2012 meningitis outbreak, which was caused by contaminated drugs sold by an unregulated compounding pharmacy, was a direct result of this crisis. After two FDA-regulated generic drug makers stopped making a widely-used steroid pain killer because it had become unprofitable, many providers were forced to buy this medication from now-shuttered New England Compounding Center (NECC).

- Years before the drug shortages made headlines, four Senate Antitrust Subcommittee hearings, federal and state investigations, media exposés, antitrust lawsuits and independent academic studies found that GPOs, instead of saving money for hospitals by purchasing in bulk, actually inflated healthcare costs.

- Various investigations revealed that many GPO and hospital executives have enriched themselves personally through this system. GPO executives have received stock options in firms they do business with, while hospital officials have gotten "patronage fees" and "sharebacks" from GPOs and lavish perks from suppliers.

- Thanks to aggressive GPO/PBM lobbying and campaign contributions, there is virtually no disclosure, transparency, regulation, or oversight of the powerful, secretive GPO/PBM industry. Few, if any, outsiders know where the billions of dollars are going.

ACTION ITEM/RECOMMENDATIONS

Physicians for Reform (PFR) is helping assemble and lead a broad network of organizations to reframe the healthcare debate and lay out a free-market, patient centered vision for the future of American healthcare. Repealing the "Safe Harbor" law is the first of twelve separate reforms.

Physicians Against Drug Shortages (PADS) is a key member of this network. For the past six years Dr. Robert Campbell, PADS chair and co-founder, and his colleagues have investigated this issue at the highest levels. They have concluded there is no path to affordable, high quality healthcare until free-market competition is restored to the drug/medical supply marketplace. This is possible only if Congress repeals the 1987 Medicare anti-kickback "Safe Harbor" provision.

Legislation has already been drafted in both the House and the Senate. However, we must change the politics of the issue through public education before these bills can be successfully brought to the floor. This represents a unique and historic opportunity to save money, save lives, and make American healthcare great again.

Please contact me if I can be of further service.

Sincerely,

CL Gray, MD
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