1601 N. Tucson Blvd. Suite 9
Tucson, AZ 85716-3450
(800) 196 or (520) 327-4885
FAX (520) 326-3529 or 325-4230
www.aapsonline.org

Association of American Physicians and Surgeons, Inc.
A Voice for Private Physicians Since 1943
Omnia pro aegroto

March 9, 2024

Comments submitted in response to FTC-2024-0018, Solicitation for Public Comment to Understand Lack of Competition and Contracting Practices that May be Contributing to Drug Shortages

Request for Oversight of the Anti-Competitive Practices of Hospital Group Purchasing Organizations (GPOs)

Thank you for the opportunity to submit comments on behalf of the Association of American Physicians and Surgeons (AAPS). Founded in 1943, AAPS represents physicians in every state and virtually every specialty caring for millions of patients across the nation.

In these comments we urge the FTC and HHS to increase oversight of hospital Group Purchasing Organizations, commonly referred to as GPOs.

We applaud your past efforts to shine a light on, and reform, the anti-competitive practices of Pharmacy Benefits Managers (PBMs). Such practices result in both higher prices for patients and degradation of quality of care through delays and formulary decisions driven by kickbacks instead of what is best for a patient. Similarly egregious activities are common among the GPOs that control purchasing of supplies, devices, and medications for hospitals. In short, GPOs are interfering with our ability as physicians to provide excellent medical care for our patients, especially the most vulnerable patients who require surgery, hospitalization, or other complex treatments.

For example, CBS's *60 Minutes*[1] recently explored how secret fees that are paid to GPOs by drug, device, and supply manufacturers, along with other hidden contractual terms GPOs impose on hospitals and others, bear responsibility for shortages of items ranging from things as simple as sterile water to crucial drugs used to treat childhood leukemia, like Vincristine. These schemes also appear to share culpability for the dire shortage of contrast dye used in medical scans that is currently plaguing the practice of medicine.[2]

[1] Transcript: https://www.cbsnews.com/news/generic-drugs-pharmaceutical-companies-60-minutes-2022-05-22/, Video: https://60min.cimediacloud.com/mediaboxes/fad17157897c42f18e4b03e0fde34b76

[2] https://mattstoller.substack.com/p/buckraking-did-a-medical-monopolist

The abuses, driven by safe harbors to the Anti-Kickback Statute (AKS), permitted by Congress in 1986[3] and subsequent regulation, go back decades. In 2002, neonatologist Mitch Goldstein, MD, testified to the Senate Judiciary Committee about how GPO contracting provisions prevent Loma Linda University Medical Center from replacing unsafe pulse oximeters, crucial for monitoring breathing in newborns, with accurate devices.[4]

COVID-19 has only exacerbated the exploitation. "The pandemic of 2020 has now unmasked the ugliness behind the shortages in America's healthcare supply chain," and GPOs are taking advantage of the crisis, explains pediatrician Marion Mass, MD.[5] For example GPO anticompetitive practices are impeding hospitals from obtaining personal protective equipment (PPE), putting both patients and clinicians at risk. "[E]ven when PPE was donated, GPO middlemen blocked the donations from getting into hospitals," Dr. Mass notes.

A 2021 Biden White House report on Building Resilient Supply Chains helps connect the dots on how this occurs:[6]

> GPO contracting practices may lead to limits in diversification of supply. GPOs may contract with certain manufacturers that are willing to pay to become a sole supplier. GPOs may also further link discounts to hospitals to sole supplier contractual arrangements. These two practices can lead to one or two manufacturers serving an entire regional or national supply chain.

As the White House report implies, contracts that GPOs have with hospitals and manufacturers incentivize kickbacks. The White House analysis echoes a 2014 Government Accountability Office (GAO) report to Congress examining the impact of GPOs on increasing Medicare costs. In it, the GAO expresses concerns about protection of kickbacks, stating, "repealing the safe harbor could eliminate misaligned incentives."[7]

To ensure GPO contracts are in compliance with available safe harbors to the AKS,[8] HHS has authority to review both the contracts and information about payments made under the contracts. Unfortunately, HHS very rarely exercises its oversight authority. HHS admitted to the GAO that, "since 2004, the office has not, as a routine matter, requested that GPOs disclose to the Secretary of HHS the amount of contract administrative fees received from each vendor with respect to purchases made by or on behalf of GPOs' customers."[9] And the amount of fees is anything but trivial. "[T]he current system may inflate costs by 30% or more," explain Phil Zweig, MBA and Frederick Blum, MD of Physicians Against Drug Shortages, in the *Wall Street Journal*.[10] Mr.

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[3] PL 99-509 https://www.congress.gov/99/statute/STATUTE-100/STATUTE-100-Pg1874.pdf

[4] https://www.judiciary.senate.gov/imo/media/doc/goldstein_testimony_04_30_02.pdf

[5] https://www.texaspolicy.com/its-time-for-a-great-reformation-in-health-care-spending/

[6] https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply-chain-review-report.pdf

[7] https://www.gao.gov/assets/gao-15-13.pdf

[8] https://www.law.cornell.edu/uscode/text/42/1320a-7b, https://www.law.cornell.edu/cfr/text/42/1001.952

[9] https://www.gao.gov/assets/600/590534.txt

[10] https://www.wsj.com/articles/where-does-the-law-against-kickbacks-not-apply-your-hospital-1525731707

Zweig estimated in 2018 that by repealing counterproductive safe harbors available to GPOs, "the savings to Medicare and Medicaid would amount to about $37 billion per year."[11]

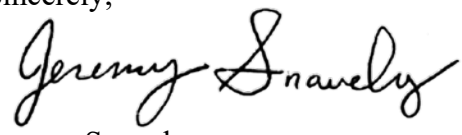
Physicians across the United States are uniting to call for action on this issue. Due to concern about how kickbacks to GPOs are driving shortages of the drugs and supplies they need to treat patients, physicians in the American College of Emergency Medicine adopted a resolution advocating for a repeal of safe harbors that protect kickbacks in the supply chain.[12] Organizations of physicians in all specialties, like the the American Medical Association,[13] Association of American Physicians and Surgeons,[14] Practicing Physicians of America,[15] Physicians for Reform, and Physicians Against Drug Shortages,[16] to name a few, are also advocating for an end to practices that benefit middlemen at the expense of patient care.

So we are writing to you today on behalf of physicians who are caring for our nation's patients to ask for your assistance. If we may respectfully suggest, a good place to start would be to consider asking GPOs, hospitals, and manufacturers, to submit relevant contracts between them for review. Transparency concerning what terms are in them, especially when taxpayer funds are involved in funding most of the purchases, is the first essential step in crafting a solution that will address the harm to patients and restore our capacity to properly treat their medical needs.

Thank you for considering our urgent request. Patients' lives are on the line. "The time has come to do what is best for patients and to restore integrity, competition, choice, and cost savings to the purchasing process," as Marilyn M. Singleton, MD, JD, concludes in her analysis, "Group Purchasing Organizations: Gaming the System."[17]

We would welcome the opportunity to meet with you and your staff to further discuss this request and address these challenging problems.

Sincerely,



Jeremy Snavely
Director of Regulatory Affairs
[redacted]

[11] https://downloads.regulations.gov/HHSIG-2018-0002-0261/attachment_3.pdf

[12] https://bit.ly/ACEPGPO

[13] https://www.ama-assn.org/system/files/2019-07/a19-cms-report-5.pdf

[14] https://aapsonline.org/aaps-asks-senate-finance-committee-to-address-repeal-of-gpo-pbm-anti-kickback-safe-harbor/

[15] https://practicingphysician.org/scrubs-vs-suits-the-battle-inside-the-nations-hospitals-part-2/

[16] https://www.physiciansagainstdrugshortages.com/

[17] https://www.jpands.org/vol23no2/singleton.pdf