

REPORT 8 OF THE COUNCIL ON MEDICAL SERVICE (A-19)
Group Purchasing Organizations and Pharmacy Benefit Manager Safe Harbor
(Reference Committee G)

EXECUTIVE SUMMARY

At the 2018 Annual Meeting, the House of Delegates referred Resolution 252, which was introduced by the Organized Medical Staff Section and assigned for study to the Council on Medical Service with assistance from the Council on Legislation. Resolution 252-A-18 asked: that our American Medical Association (AMA): (1) collaborate with medical specialty partners, patient advocacy groups, and other stakeholders to seek repeal of the 1987 Safe Harbor exemption to the Medicare Anti-Kickback Statute for Group Purchasing Organizations (GPOs) and Pharmacy Benefit Managers (PBMs); (2) educate its members on how safe harbor exemption for GPOs and PBMs affects drug prices and drug shortages; and (3) reaffirm Policy H-100.956, which states in part that “Our AMA will collaborate with medical specialty partners in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.”

Although the Council agrees with the sentiment that the GPO safe harbor is flawed, the Council finds little empirical evidence exists to definitively assess the impact of the GPO safe harbor. Most research studies are funded by interested parties, and a limited economic model with no funding ties to GPOs, PBMs, or proponents of repeal, found that while removal of the safe harbor decreased providers’ nominal purchasing price, their total purchasing costs are the same as when the safe harbor was present. Thus, repeal would not affect any party’s profits or costs. In a broader economic model, a study found that total purchasing cost of the providers is not affected by the presence of the GPO administration fees, although providers may experience higher unit prices. Accordingly, the Council recommends reaffirming Policy H-100.956 calling for collaboration with medical specialty partners in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.

Additionally, the Council is concerned that, if the GPO safe harbor is repealed, GPOs and PBMs could simply shift fees into other forms, such as rebates or other fees, rather than lose their revenue stream. Moreover, the Council believes that repeal of the GPO safe harbor could create widespread disruption of the supply chain and administrative challenges for not only hospitals (including physician-owned hospitals), but also clinics, ambulatory surgery centers, and other provider arrangements. As such, physician-owned practice settings may be adversely impacted if the viability of the GPO business model is compromised. Whatever the defects in their funding structure, the Council finds that GPOs serve a function in enabling cost savings and efficiencies in procurement to facilitate patient care. Accordingly, the Council recommends renewing efforts urging the federal government to support greater public transparency and accountability efforts involving the contracting mechanisms and funding structures subject to the GPO and PBM anti-kickback safe harbor, including the potential impact on drug pricing and drug shortages. The Council also recommends supporting efforts to update and modernize the fraud and abuse laws and regulations to address changes in the health care delivery and payment systems including the potential impact on drug pricing and drug shortages.

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 8-A-19

Subject: Group Purchasing Organizations and Pharmacy Benefit Manager Safe Harbor
(Resolution 252-A-18)

Presented by: James G. Hinsdale, MD, Chair

Referred to: Reference Committee G
(Rodney Trytko, MD, Chair)

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2 introduced by the Organized Medical Staff Section and assigned for study to the Council on
3 Medical Service with assistance from the Council on Legislation. Resolution 252-A-18 asked:

4
5 That our American Medical Association (AMA): (1) collaborate with medical specialty
6 partners, patient advocacy groups, and other stakeholders to seek repeal of the 1987 Safe
7 Harbor exemption to the Medicare Anti-Kickback Statute for Group Purchasing Organizations
8 (GPOs) and Pharmacy Benefit Managers (PBMs); (2) educate its members on how safe harbor
9 exemption for GPOs and PBMs affects drug prices and drug shortages; and (3) reaffirm Policy
10 H-100.956, which states in part that “Our AMA will collaborate with medical specialty
11 partners in identifying and supporting legislative remedies to allow for more reasonable and
12 sustainable payment rates for prescription drugs.”

13
14 This report provides background on GPOs, how they function, and the relevant federal anti-
15 kickback statute; details how the GPO safe harbor is used by PBMs; outlines possible antitrust and
16 anticompetitive concerns with the GPO safe harbor; specifies the possible legal and patient access
17 implications of repeal of the safe harbor; and offers recommendations to refine the GPO safe
18 harbor operations.

19 20 BACKGROUND

21
22 At the 2016 Annual Meeting, Resolution 201-A-16, “Repeal of Anti-Kickback Safe Harbor for
23 Group Purchasing Organizations,” sponsored by the Medical Student Section, asked the AMA to
24 support the repeal of the Anti-Kickback safe harbor for GPOs. Resolution 201-A-16 was referred
25 for decision by the House of Delegates. The Council on Legislation discussed and provided input
26 for the Management Report for Board Action, which recommended not adopting Resolution
27 201-A-16. The Board voted that Resolution 201-A-16 not be adopted.

28
29 At the 2018 Annual Meeting, concern was raised during the reference committee hearing regarding
30 Resolution 252-A-18 that its proposed solution of repealing the GPO safe harbor could be both
31 ineffective and counterproductive in addressing the identified problems of drug shortages and
32 pricing. With respect to GPO pricing incentives, testimony also stated that GPO contracts are
33 voluntary in nature. GPO customers may have the ability to purchase products and services off-
34 contract if they find a preferable or better-priced option. Testimony further indicated that GPO
35 customers include not only hospitals, but also clinics, ambulatory surgery centers, and other

1 provider arrangements. As such, physician-owned hospitals and other physician practice settings
 2 may be adversely impacted if the viability of the GPO business model is compromised.

3
 4 **HOW A GPO FUNCTIONS**

5
 6 GPOs are organizations that act as purchasing intermediaries that negotiate contracts between their
 7 customers—health care providers—and vendors of medical products. A GPO is generally made up
 8 of provider-members, and such members may receive profits from the GPO. A provider joins a
 9 GPO to “incur a lower purchasing cost . . . by buying through the GPO [rather] than by contracting
 10 for the same item directly with a manufacturer. GPOs assert that they are able to lower their
 11 provider-members’ price per unit by employing market intelligence and product expertise that no
 12 single member could afford, and by contracting for the group’s combined purchase quantity. GPOs
 13 are able to lower a provider’s contracting cost by spreading its own, presumably higher, fixed
 14 contracting cost over its many members.”¹ For example, AMA members can receive practice
 15 discounts through Henry Schein Medical for medical, surgical, pharmaceutical, and equipment
 16 purchases.² Henry Schein is partnered with GroupSource, a GPO serving the non-acute physician
 17 market, to offer physicians a wide range of products.³

18
 19 GPOs earn revenue from several sources:

- 20 • Administrative fees paid by the manufacturer of products;
 21 • Membership fees from provider-members;
 22 • Administrative fees charged to distributors authorized to distribute products under a GPO’s
 23 contract;
 24 • Miscellaneous service fees that are charged directly to provider-members; and
 25 • Other sources of revenue like outside investments.

26
 27 GPOs offer a variety of services that may be paid by the administration fees or through direct
 28 charging to provider members. The U.S. Government Accountability Office identifies the funding
 29 methods that GPOs reported using for the services they provided:⁴

Table 3: The Six Largest Group Purchasing Organizations’ (GPO) Reported Funding Methods for Services Provided in 2008

Service ^a	Number of GPOs offering service	Number of GPOs funding only through administrative fees	Number of GPOs funding only through charges to customers	Number of GPOs using both funding methods
Custom contracting	6	2	2	2
Clinical evaluation and standardization	6	4	0	2
Technology assessments	6	5	1	0
Supply-chain analysis	5	1	1	3
Electronic commerce	5	2	0	3
Materials management consulting	5	1	1	3
Benchmarking data	5	1	1	3
Continuing medical education	5	4	0	1
Market research	4	2	2	0
Materials management outsourcing	3	0	3	0
Patient safety services	3	2	1	0
Marketing products or services	3	2	1	0
Insurance services	2	1	1	0
Revenue management	2	0	2	0
Warehousing	1	1	0	0
Equipment repair	1	1	0	0
Other ^b	3	2	0	1

1 STATUTORY AND REGULATORY BACKGROUND ON THE FEDERAL ANTI-KICKBACK
 2 STATUTE

3
 4 The federal anti-kickback statute provides *criminal* penalties for individuals or entities that
 5 knowingly and willfully offer, pay, solicit, or receive remuneration to induce business reimbursed
 6 under the Medicare or state health care programs.⁵ The offense is classified as a felony, and is
 7 punishable by fines of up to \$100,000, imprisonment for up to 10 years, and subjects the offending
 8 party to false claims act liability. The Secretary of the US Department of Health and Human
 9 Services (HHS) delegated authority over the anti-kickback statute to the HHS Office of Inspector
 10 General (OIG).

11
 12 This provision is extremely broad. The types of remuneration covered specifically include
 13 kickbacks, bribes, and rebates made directly or indirectly, overtly or covertly, or in cash or in kind.
 14 In addition, prohibited conduct includes not only remuneration intended to induce referrals of
 15 patients, but also intended to induce the purchasing, leasing, ordering, or arranging for any good,
 16 facility, service, or item paid for by Medicare or state health care programs.

17
 18 Because of the broad reach of the statute, concern was expressed that some relatively innocuous
 19 commercial arrangements were covered by the statute and, therefore, potentially subject to criminal
 20 prosecution. In response, Congress provides statutory exceptions from illegal remuneration where
 21 the anti-kickback statute does not apply. In addition, Congress specifically required the
 22 development and promulgation of regulations, the so-called safe harbor provisions, that would
 23 specify various payment and business practices that would not be treated as criminal offenses under
 24 the anti-kickback statute, even though they may potentially be capable of inducing referrals of
 25 business under federal health care programs.⁶ In authorizing HHS to protect certain arrangements
 26 and payment practices under the anti-kickback statute, Congress intended that the safe harbor
 27 regulations be updated periodically to reflect changing business practices and technologies in the
 28 health care industry.

29
 30 Accordingly, the legal framework governing the anti-kickback statute includes both statutory
 31 exceptions *and* regulatory safe harbors. The federal government considers the statutory exceptions
 32 and regulatory safe harbors as co-terminus, meaning that they cover the same conduct and the
 33 regulatory safe harbor is implementing the statutory safe harbor. Industry and the provider
 34 community have argued that they are distinct, separate protections. For example, a provider could
 35 receive protection under the statutory exception for discounts even if the arrangement would not fit
 36 within the counterpart regulatory safe harbor. Whether the protections are co-terminus or distinct is
 37 an open legal question that depends on the legal precedent of case law in each federal circuit (if a
 38 circuit has considered this specific issue).

39
 40 This report will focus on three specific statutory exceptions and regulatory safe harbors that may
 41 cover the various funding mechanisms of GPOs: (1) GPO safe harbor; (2) discount safe harbor; and
 42 (3) personal services and management contracts safe harbor.

43
 44 *GPO Statutory Exception and Regulatory Safe Harbor*

45
 46 With GPOs, Congress enacted section 9321 of the Omnibus Budget Reconciliation Act of 1986,
 47 which excludes from the definition of “remuneration” certain fees paid by vendors to GPOs from
 48 prosecution under the anti-kickback statute.⁷ According to the legislative history, Congress
 49 believed that GPOs could “help reduce health care costs for the government and the private sector
 50 alike by enabling a group of purchasers to obtain substantial volume discounts on the prices they
 51 are charged.”⁸

1 In 1991, OIG issued a final rule implementing a GPO safe harbor to apply to payments from
2 vendors to entities authorized to act as a GPO for individuals or entities who are furnishing
3 Medicare or Medicaid services. The proposed safe harbor required a written agreement between the
4 GPO and the individual or entity that specifies the amounts vendors will pay the GPO.

5
6 To qualify for protection under the GPO safe harbor, a GPO must have a written agreement with
7 each individual or entity for which items or services are furnished. That agreement must either
8 provide that participating vendors from which the individual or entity will purchase goods or
9 services will pay a fee to the GPO of three percent or less of the purchase price of the goods or
10 services provided by that vendor or, in the event the fee paid to the GPO is not fixed at three
11 percent or less of the purchase price of the goods or services, specify the amount (or if not known,
12 the maximum amount) the GPO will be paid by each vendor (where such amount may be a fixed
13 sum or a fixed percentage of the value of purchases made from the vendor by the members of the
14 group under the contract between the vendor and the GPO).

15
16 Where the entity that receives the goods or services from the vendor is a health care provider of
17 services, the GPO must disclose in writing to the entity at least annually, and to the Secretary upon
18 request, the amount received from each vendor with respect to purchases made by or on behalf of
19 the entity. As explained in the preamble to the final regulations, the safe harbor is not intended to
20 protect fees to arrange for referrals or recommendations within a single entity.⁹ Therefore, the safe
21 harbor provides that “Group Purchasing Organization” means an entity authorized to act as a
22 purchasing agent for a group of individuals or entities who are furnishing services for which
23 payment may be made in whole or in part under Medicare, Medicaid, or other federal health care
24 programs, and who are neither wholly owned by the GPO nor subsidiaries of a parent corporation
25 that wholly owns the GPO (either directly or through another wholly owned entity).

26
27 Thus, if a GPO meets the above requirements, it fits within the GPO safe harbor and its
28 administrative fees will not be subject to criminal prosecution under the anti-kickback statute. Of
29 course, these administrative fees may cover a variety of services.

30
31 *Discount Statutory Exception and Regulatory Safe Harbor*

32
33 The discount statutory exception applies to arrangements where there is a discount or other
34 reduction in price that was obtained by a provider or other entity when such discounts are properly
35 disclosed and reflected in the costs for which reimbursement could be claimed.¹⁰ Congress included
36 the discount exception to “ensure that the practice of discounting in the normal course of business
37 transactions would not be deemed illegal.”¹¹

38
39 The regulatory discount safe harbor exempts from the definition of remuneration discounts on
40 items or services for which the federal government may pay and certain disclosure requirements
41 are met.¹² A discount means a reduction in the amount a buyer is charged for an item or service
42 based on an arms-length transaction. In addition, rebates are also covered under the discount safe
43 harbor to mean an amount that is described in writing at the time of the purchase but is not paid at
44 the time of sale. The safe harbor also specifically excludes from the definition of a discount cash or
45 cash-equivalents (except for rebates in the form of a check); certain swapping arrangements
46 (e.g., induce purchasing one good for another good); exempted remuneration from other safe
47 harbors (e.g., warranties); and other remuneration, in cash or in kind not explicitly described by
48 the safe harbor.

1 The regulatory safe harbor disclosure requirements vary based on the type of entity—buyer, seller,
2 offeror—in the discount arrangement. Moreover, a buyer’s disclosure requirements depend on
3 whether the entity is (1) acting under a risk contract; (2) reports costs on a cost report; or
4 (3) submits a claim or a request for payment is submitted for the discounted item or service and
5 payment may be made, in whole or in part, under Medicare, Medicaid, or other federal health care
6 programs.¹³

7
8 Thus, a GPO’s up-front discount is covered by the statutory exception and the regulatory safe
9 harbor if properly disclosed, and it will not be subject to criminal prosecution under the anti-
10 kickback statute.

11 *Personal Services and Management Contracts Regulatory Safe Harbor*

12
13
14 This safe harbor protects certain payments made by a principal to an agent as compensation for the
15 agent’s services. Protection applies only if certain standards are met that “limit the opportunity to
16 provide financial incentives in exchange for referrals.”¹⁴ These standards include that aggregate
17 compensation is set in advance, consistent with fair market value in an arms-length transaction, and
18 not determined in a manner that takes into account the volume or value of any referrals or business
19 generated between the parties.¹⁵

20
21 Thus, if a GPO offers additional services that go beyond the administration fees (i.e., direct charges
22 to the provider-members), the GPO may be able to structure such fees under the personal services
23 safe harbor and receive protection from criminal prosecution under the anti-kickback statute.

24 APPLICATION TO PHARMACY BENEFIT MANAGERS

25
26
27 Overall, the application of the anti-kickback safe harbors and exceptions to PBMs is difficult
28 because PBMs and their current activities were not prevalent or existent when the safe harbors
29 were created.

30 *GPO Statutory Exception and Regulatory Safe Harbor*

31
32
33 The OIG’s only formal pronouncement on PBMs and the GPO regulatory Safe Harbor is found in
34 sub-regulatory guidance: Compliance Program Guidance for Pharmaceutical Manufacturers issued
35 in 2003.¹⁶ “Any rebates or other payments by drug manufacturers to PBMs that are based on the
36 PBM’s customers’ purchases potentially implicate the anti-kickback statute.” Protection is
37 available by structuring such arrangements to fit in the GPO safe harbor. That safe harbor requires,
38 among other things, that the payments be authorized in advance by the PBM’s customer and that all
39 amounts actually paid to the PBM on account of the customer’s purchases be disclosed in writing
40 at least annually to the customer and to HHS upon request. In addition, Medicare Part D sponsors
41 and other entities that provide PBM services are required to report various data elements to CMS.
42 The statute specifies that this data is confidential and generally must not be disclosed by the
43 government or by a plan receiving the information.¹⁷

44
45 The OIG potentially extended the GPO regulatory Safe Harbor, which is meant to cover
46 administrative fees, to include “any rebates or other payments.” Thus, PBMs can argue that fees
47 and rebates have protection under the GPO Safe Harbor. However, PBMs would attempt to fit non-
48 administrative fees within different safe harbors first and then potentially rely on GPO Safe Harbor
49 as a backstop.¹⁸

1 *Discount Statutory Exception and Regulatory Safe Harbor*

2
 3 On February 6, 2019, HHS issued a proposed rule to amend the safe harbor regulations concerning
 4 discounts.¹⁹ HHS is proposing to disallow these traditional discount/rebate arrangements for plan
 5 sponsors under Part D and Medicaid Managed Care Organizations and attempt to instead pass any
 6 price concession directly to the beneficiary at the point-of-sale of the drug. To do this, they are
 7 proposing changes to the anti-kickback safe harbor regulation concerning discounts. Under the
 8 proposal, CMS would eliminate the current safe harbor protections for discounts paid by
 9 manufacturers directly to plan sponsors and PBMs. HHS also proposes the creation of two new
 10 safe harbor protections: protection for reductions in price at the point-of-sale and protection for
 11 fixed fees paid to PBMs for services rendered to manufacturers.²⁰

12
 13 In its formal response to the proposed rule, the AMA commented that OIG either needs to
 14 eliminate the application of the GPO regulatory safe harbor to PBMs or clarify its application only
 15 to administrative fees and define what services are covered. The AMA’s comments went on to state
 16 that PBMs may be able to avail themselves to existing regulatory safe harbors including the GPO
 17 safe harbor, the personal services and management contracts safe harbor, managed care safe harbor,
 18 and the proposed certain PBM services safe harbor. The AMA requested that the Department
 19 clarify what PBM fees and services apply to both the proposed and existing safe harbors.
 20 Otherwise, the AMA is concerned that the lack of clarity may provide further opportunity for
 21 exploitation.

22
 23 Moreover, on May 16, 2018, Secretary Azar noted: “We would welcome the PBM industry coming
 24 forth with broader proposals for moving away from today’s system, including a plan for
 25 implementation with the pharmaceutical industry. But we also have the administrative power to
 26 end this system ourselves—to eliminate rebates and forbid remuneration from pharmaceutical
 27 companies, align interests, and end the corrupt bargain that keeps driving list prices skyward.” In
 28 his comments before the Senate Health, Education, Labor & Pensions Committee, Secretary Azar
 29 went further, noting: “Rebates are allowed under an exception to the Anti-Kickback Statute, and
 30 that’s an exception that we believe by regulation we could modify.”

31
 32 In the legal community, there is debate as to whether a PBM truly meets the definition of a “buyer”
 33 under the regulatory discount safe harbor considering PBMs do not take physical possession of the
 34 drugs. That said, most discount arrangements between PBMs and drug manufacturers (or other
 35 entities) are structured to fit within the discount safe harbor.

36
 37 *Personal Services and Management Contracts Regulatory Safe Harbor*

38
 39 As with GPOs, if a PBM offers additional services that go beyond the administration fees
 40 (e.g., data analytics, disease management), the PBM may be able to structure such fees under
 41 the personal services safe harbor and receive protection from criminal prosecution under the
 42 anti-kickback statute.

Summary Table

	GPO	PBM	Anti-Kickback Statute exception/safe harbor
Administrative Fees	~3%	~4.5-5% ²¹	Protected by the GPO safe harbor
Type of Discount	Up front <u>discount</u> at time of purchase	After the purchase <u>rebate</u>	Protected by the Discount safe harbor
Other fees	Data analytics, market research, clinical evaluation, etc.	Data analytics, disease management	If applicable, protected by the Personal Services safe harbor

1 ANTITRUST AND COMPETITION CONCERNS

2
 3 In response to antitrust concerns in the health care area, the Department of Justice (DOJ) and the
 4 Federal Trade Commission (FTC) from 1993-1996 issued policy statements involving mergers and
 5 various joint activities in the health care arena.²² Statement 7 discusses DOJ/FTC enforcement
 6 policy involving health care providers’ joint purchasing agreements, which includes GPOs.
 7 Generally, DOJ/FTC believe that most joint purchasing arrangements among hospitals or other
 8 health care providers do not raise antitrust concerns because the participants frequently can obtain
 9 volume discounts, reduce transaction costs, and have access to other services like consulting advice
 10 that may not be available to each participant on their own. Absent extraordinary circumstances, the
 11 agencies will not challenge any joint purchasing arrangement if it is in the “Antitrust Safety Zone.”

12
 13 Two conditions must be present to enter the zone:

- 14
 15 (1) The purchases by the health care provider account for less than 35 percent of the total sales
 16 of the purchased product or services in the relevant market.
 17 (2) The cost of the products and services purchased jointly accounts for less than 20 percent of
 18 the total revenue from all products or services sold by each competing participant in the
 19 joint purchasing arrangements.
 20

21 The agencies also listed certain safeguards that joint purchasing arrangements can adopt to
 22 minimize concerns including not requiring the use of arrangements for all services; having an
 23 independent employee or agent negotiate on behalf of the joint purchasing arrangement, and
 24 ensuring communications between the purchasing group and participants are kept confidential.
 25

26 Since this guidance was issued, GPO market consolidation has increased and led to an oligopoly
 27 market structure for national GPOs. The five largest GPOs by purchasing volume have
 28 approximately 85-90 percent of the market²³ and in 2017 the top four GPOs reported a total
 29 purchasing volume of \$189 billion.²⁴
 30

31 Competition concerns are also raised when it comes to contracts between GPOs and vendors
 32 including sole-source contracting, minimum purchasing requirements that may cause overspending,
 33 length of the contract (5+ years in some instances), and bundling.
 34

- 35 • Sole-source contracts: In a GAO report, all five major GPOs reported that they do
 36 negotiate sole-source contracts when it is advantageous to their customers, though some
 37 GPOs reported negotiating a higher proportion of sole source contracts than others. One
 38 GPO said that about 18 percent of its customers’ spending through the GPO is through
 39 sole-source contracts. Three GPOs reported sole-source contracting for branded drugs and

- 1 commodities, and four GPOs reported sole-source contracting for generic drugs, including
 2 generic injectable drugs.
- 3 • Contracts that bundle related products: GPOs report negotiating contracts that offer
 4 discounts based on the purchase of bundled products, but restricting bundling to products
 5 that are used together or are otherwise related in order to create efficiencies and help
 6 standardize products for their customers.
 - 7 • Long-term contracts: GPOs report awarding longer terms for certain types of products,
 8 such as IV systems and laboratory products.

9
 10 Alternatively, all GPO contracts are voluntary and the product of market negotiations. Hospitals
 11 and other health care providers are generally not required to only contract with one GPO and may
 12 belong to multiple GPOs. Vendors are not required to contract with GPOs and health care
 13 providers are not required to use the contracts negotiated by GPOs with their vendors. While GPOs
 14 may negotiate sole-source contracts, providers are generally not required to purchase through their
 15 GPO contracts but can instead purchase supplies “off contract” by negotiating their own prices
 16 directly with suppliers.²⁵ In economic models, on-contract prices are not necessarily the lowest
 17 available. In fact, off-contract prices are sometimes lower. However, off-contract prices could be
 18 lower than on-contract prices because of the presence of the GPO. Without the GPO, the off-
 19 contract price could potentially be higher.²⁶

20
 21 In addition to the above concerns related to GPO contracts, PBM contracting mechanism may also
 22 have an impact on competition. Complaints about the PBM contracting process include employers
 23 wanting an alternative to a rebate-driven approach to managing costs, PBMs lacking transparency
 24 about how they generate revenue, contracts being complicated and including clauses that benefit
 25 the PBM at the expense of the employer or patient, and rebates contributing to misaligned
 26 incentives that put PBM interests before patients or employers (no fiduciary obligation).²⁷

27
 28 *Contributing Factors to Drug Shortages*

29
 30 Drug shortages remain an ongoing public health concern in the United States. Although the rate of
 31 new shortages has decreased, long-term active and ongoing shortages have not been resolved and
 32 critical shortages continue to impact patient care and pharmacy operations. Several commonly used
 33 products required for patient care are in shortage including sterile infusion solutions (e.g., saline,
 34 amino acids, dextrose), as well as diazepam, lidocaine, hydromorphone, and morphine.

35
 36 Proponents supporting the repeal of the GPO Safe Harbor state the root cause of drug shortages is
 37 the existence of the GPO Safe Harbor.²⁸ However, the drug shortage issue is multi-factorial and
 38 complex. Ongoing supply challenges of certain medications, typically injectable products that are
 39 off-patent and have few suppliers, persist. Causes of these shortages continue to remain largely
 40 unchanged:

- 41
 42 • Quality problems – drug shortages are mostly triggered by quality problems during
 43 manufacturing processes which cause manufacturers to slow or halt production to address
 44 these problems.
- 45 • Limited inventory – widespread use of just-in-time inventory practices can increase the
 46 vulnerability of the supply chain to shortages.
- 47 • Regulatory approval – new manufacturers may not be able to quickly enter the market to
 48 produce a drug in shortage because the U.S. Food & Drug Administration’s (FDA)
 49 approval is required. Existing manufacturers also need FDA approval of changes to
 50 manufacturing conditions or processes.

- 1 • Production complexity – costly, specialized equipment is required to manufacture drugs
2 and maintaining sterility throughout the production process is challenging and may require
3 facilities dedicated solely to those drugs.
- 4 • Constrained manufacturing capacity – in the generic sterile injectable market, the industry
5 is concentrated and has limited manufacturing capacity. The pressures to produce many
6 drugs on only a few manufacturing lines can leave manufacturers with little flexibility
7 when one manufacturer ceases production of a particular drug.

8
9 With respect to GPOs, a 2014 GAO report in examining causes of drug shortages was inconclusive
10 and, importantly, did not mention the GPO safe harbor as a causal factor of drug shortages.²⁹
11 Accordingly, while the presence of the GPO safe harbor may be a factor in drug shortages, drug
12 shortages are multi-factorial, no consensus exists as to what percentage, if any, the safe harbor
13 contributes to drug shortages, and no empirical evidence exists that the safe harbor is the root cause
14 of drug shortages.

15
16 *Contributing Factors to Drug Pricing*

17
18 Proponents supporting the repeal of the GPO Safe Harbor also state that the safe harbor causes
19 unprecedented drug price spikes.³⁰ While impacted by supply chain dynamics, other contributing
20 factors to pharmaceutical pricing include the type of pharmaceutical (generic, brand, biologic),
21 level of negotiation authority of the purchasing entity, and market exclusivity and manipulations.
22 At the front-end, pharmaceutical manufacturers set a drug’s list price, which does not include
23 discounts or rebates. The list price is set to cover costs of production, research and development,
24 and profits. Patients who are uninsured and in high-deductible health plans have greater exposure
25 to the list price; for other patients who are insured, it more represents a starting price in the
26 distribution chain from wholesalers to pharmacies to patients, ultimately impacting patient cost-
27 sharing levels. While concerns have been raised that the rebate process between pharmaceutical
28 companies and PBMs results in list prices above what they would be absent rebates, other key
29 factors foundationally impact a drug’s list price.

30
31 When addressing the pricing of brand-name drugs, such factors include the number of individuals
32 expected to use the drug, development costs, and competition in the marketplace. Brand-name
33 drugs have 20 years of patent protection from the date of filing, and also enjoy a period of market
34 exclusivity, depending on the type of drug. Orphan drugs – drugs to treat rare diseases or
35 conditions affecting less than 200,000 individuals in the U.S., or affecting more than 200,000
36 individuals but for which there is not a reasonable expectation that the sales of the drug would
37 recover the costs – have seven years of market exclusivity. Drugs deemed to be innovative
38 products that include an entirely new active ingredient – a new chemical – have five years of
39 market exclusivity. Six months of exclusivity are added to existing exclusivity periods once studies
40 on the effects of a drug upon children are submitted for FDA review and meet the statutory
41 requirements.³¹

42
43 Currently, biologic manufacturers have 12 years of market exclusivity for innovator products.
44 Innovator biologics also have additional patent protection that generally exceeds the market
45 exclusivity period by a few years. Overall prices for biologics are higher resulting from the high
46 risk and expense of manufacturing these products, the special handling and administration required,
47 and an overall lack of competition in the marketplace. Biosimilars can offer some cost savings in
48 comparison with their originator equivalents, but thus far not at the level seen between traditional
49 brand-name and generic drugs.

1 Brand-name drug manufacturers have also used various techniques to delay competition in the
 2 marketplace or lengthen patent protection. In reverse-payment patent litigation settlements, also
 3 known as “pay-for-delay” settlements, a brand-name drug manufacturer pays a potential generic
 4 competitor to abandon its patent challenge and delay offering a generic drug product for a number
 5 of years. Brand-name manufacturers can also attempt to effectively extend the term of patent
 6 protection for a single product by creating a patent portfolio, composed of patents with staggered
 7 terms for modified forms of the same drug, new delivery systems for that drug, or other variations
 8 of the original product, a practice known as “evergreening.” Examples of evergreening include
 9 reformulating a drug as extended release or changing the mix of chemical isomers. In situations
 10 where a newer version of an existing brand-name drug enters the marketplace, brand-name
 11 manufacturers can also choose to take the older drug off the market or restrict access to the older
 12 drug, including by limiting its distribution through select specialty pharmacies.

13
 14 Several factors can impact the prices of generic drugs, including drug shortages, supply
 15 disruptions, limits in manufacturing capacity, and generic drug industry mergers and acquisitions.
 16 In addition, generic drug companies may transition to manufacture drugs recently off patent to gain
 17 early market share, while others have chosen to manufacture generic drugs that have been on the
 18 market for some time and no longer have ample competition.

19
 20 Patient out-of-pocket costs for the same prescription drug can vary based on the health plan in
 21 which they are enrolled. Certain government programs, including Medicaid, the Veterans Affairs
 22 and Department of Defense, secure discounts and/or rebates on the price of prescription drugs. In
 23 most other coverage situations, patient cost-sharing levels result from insurer/PBM-pharmaceutical
 24 company negotiations, and depend on whether drugs are on their health plan formulary, and if so,
 25 at what cost-sharing tier.

26
 27 Our AMA policies on drug shortages and pricing advocate pursuing a collaborative approach
 28 focused on finding the root causes of problems. Blaming GPOs for the complicated drug shortage
 29 problem risks compromising this solution-oriented strategy, especially without a current policy
 30 consensus on this point. With respect to GPO pricing incentives, it is important to keep in mind that
 31 GPO contracts are voluntary in nature. GPO customers retain the ability to purchase products and
 32 services off-contract if they find a preferable or better-priced option.

33
 34 **DISCUSSION**

35
 36 Throughout the evolution of this report, the Council on Medical Service welcomed input from the
 37 Council on Legislation and thanks the Council on Legislation for its thoughtful comments
 38 throughout the drafting process. The Council on Medical Service is confident that the collaboration
 39 between the Councils was essential to the formulation of a measured report on a highly complex
 40 subject and the nuances therein.

41
 42 The GAO has expressly declined to call for eliminating the safe harbor as the appropriate solution,
 43 noting that “a repeal of the safe harbor provision would require a clearer understanding of the
 44 impact of the GPO funding structure.” GAO emphasized, and the Council agrees, that eliminating
 45 the safe harbor could have unintended consequences, at least in the short term:

46
 47 Some experts believe there is an incentive for GPOs to negotiate higher prices for
 48 products and services because GPO compensation increases as prices increase.
 49 However, other experts, as well as GPOs, stated that there is sufficient competition
 50 between them to mitigate any potential conflicts of interest. Almost 30 years after
 51 its passage, there is little empirical evidence to definitively assess the impact of the

1 vendor-fee-based funding structure protected under the safe harbor. While repealing
 2 the safe harbor could eliminate misaligned incentives, most agree there would be a
 3 disruption while hospitals and vendors transitioned to new arrangements. Over the
 4 longer term, if the current trend of hospital consolidation continues, the concerns
 5 about these disruptions may be diminished to the extent that large hospital systems
 6 may be in a better position to pay GPOs directly for their services or negotiate
 7 contracts with vendors on their own. Furthermore, given that some hospitals are
 8 already paying a subsidiary of one GPO directly for access to vendor contracts,
 9 alternative approaches are possible.³²

10
 11 *GPO Studies*

12
 13 As mentioned by the GAO, the Council finds little empirical evidence exists to definitively assess
 14 the impact of the GPO safe harbor. Most research studies are funded by interested parties like the
 15 Healthcare Supply Chain Association. A limited economic model with no funding ties to GPOs,
 16 PBMs, or proponents of repeal, found that while removal of the safe harbor decreased providers’
 17 nominal purchasing price, their total purchasing costs are the same as when the safe harbor was
 18 present. Thus, repeal would not affect any party’s profits or costs.³³ In a broader economic model, a
 19 study found that total purchasing cost of the providers is not affected by the presence of the GPO
 20 administration fees, although providers may experience higher unit prices.³⁴

21
 22 *Legal Impact of Fitting GPOs or PBMs Within Personal Services Safe Harbor*

23
 24 If the GPO safe harbor were repealed, the Council believes that GPOs and PBMs simply could shift
 25 fees into other forms, such as rebates or other fees, rather than lose their revenue stream. For
 26 example, the current administrative fee could fit within the personal services and management
 27 contracts safe harbor or fit within enough factors of the safe harbor that OIG would use its
 28 enforcement discretion and not pursue criminal charges against the GPO or PBM.³⁵ This safe
 29 harbor covers a wide variety of conduct. The Council notes that the personal services category
 30 covers many types of services provided in the health care industry including professional physician
 31 services provided under an independent contractor arrangement, a physician group providing
 32 medical services to a hospital, and medical director agreements. The management contracts
 33 category covers all non-professional services billing and collection, accounting, marketing,
 34 purchasing, staffing, recruiting, quality assurance, and facilities and personnel management.
 35

36 In this case, the GPO Safe Harbor three percent or 4.5 - 5 percent administration fee could be
 37 repackaged under the personal services and management contracts safe harbor as a management
 38 contract. To fit within that safe harbor, a GPO or PBM would need to meet the following
 39 requirements:

- 40
- 41 1. Agreement in writing and signed;
 - 42 2. Covers all of the services provided;
 - 43 3. Not less than one year;
 - 44 4. Aggregate compensation paid to the agent (GPO) over the term of the agreement is set in
 45 advance, is fair market value, and does not take into the volume or value of any referrals of
 46 federal health care program beneficiaries;
 - 47 5. Arrangement does not violate any state or federal law;
 - 48 6. Contracted services do not exceed what is reasonably necessary to accomplish the
 49 commercially reasonable business objective; and
 - 50 7. If services are on a part-time basis (e.g., part-time housekeeping), lay out schedule of
 51 internals, precise length, and exact charge for such intervals.

1 Repackaging the administrative fee into the personal services and management contracts safe
2 harbor may not squarely meet all of the safe harbor's requirements because a percentage may not
3 be an aggregate compensation set in advance. OIG is silent on fixed percentages laid out in
4 advance under this exception. OIG, in Advisory Opinions, does allow performance or other percent
5 bonuses as compensation even if it does not fit squarely within the safe harbor. In those instances,
6 OIG uses its enforcement discretion to decline to pursue (e.g., lack of intent). There is also a low
7 risk that the compensation (three percent) was payment for patient referrals because the percentage
8 does not directly vary with the number of patients treated. With determining fair market value, OIG
9 would likely find the three percent GPO fee or the 4.5 percent PBM fee to be fair market value
10 given the percentage of the market that uses these percentages in practice.

11
12 Moreover, specifically regarding PBMs, the Council notes that CMS Report 5-A-19, which is
13 before the House of Delegates at this meeting, recommends supporting the active regulation of
14 PBMs under state departments of insurance, supporting efforts to ensure that PBMs are subject to
15 federal laws that prevent discrimination against patients, and supporting improved transparency in
16 PBM operations including a list of disclosures.

17
18 *Impact on Patient Care*

19
20 The Council strongly believes that repeal of the GPO safe harbor may also have, at least in the
21 short-term, widespread disruption of the supply chain and administrative challenges for not only
22 hospitals (including physician-owned hospitals), but also clinics, ambulatory surgery centers, and
23 other provider arrangements. As such, physician-owned practice settings may be adversely
24 impacted if the viability of the GPO business model is compromised. Whatever the flaws in their
25 funding structure, the Council finds that GPOs serve a function in enabling cost savings and
26 efficiencies in procurement to facilitate patient care.

27
28 Accordingly, the Council believes that adopting a policy to oppose the GPO safe harbor may not
29 only hurt the AMA's credibility but also will not accomplish the objectives set forth by proponents
30 of repeal because limited economic studies show no impact on repeal, entities involved may
31 continue to operate the same practices under a different safe harbor, and repeal would potentially
32 cause a disruption of care and the supply chain.

33
34 Instead, the Council believes that the AMA should promote greater transparency and accountability
35 efforts regarding the actions covered by the GPO and PBM anti-kickback safe harbor. In 2014,
36 GAO recommended that CMS should determine whether hospitals are appropriately reporting
37 administrative fee revenues on their Medicare cost reports and take steps to address any
38 underreporting that may be found. In response, CMS issued a Technical Direction Letter to the
39 Medicare Administrative Contractors (MACs) in 2015 adding steps to the desk review program.
40 Specifically, CMS directed MACs to verify that GPO revenues have been offset where appropriate
41 in order to mitigate any risk to the Medicare program. However, nothing has been publicly released
42 based off of these desk reviews. Moreover, HHS has the capability to request records from GPOs
43 the amount received from each vendor with respect to purchases made by or on behalf of the GPOs
44 customers. Yet, the Council is unaware of any requests or public reports based off any requests
45 since the GAO report. Given the push for greater price and cost transparency and the lack of recent
46 data related to GPOs and PBMs, the Council recommends that the federal government renew
47 efforts to support greater public transparency and accountability efforts involving the contracting
48 mechanisms and funding structures subject to the GPO and PBM anti-kickback safe harbor.

49
50 Additionally, the Council believes that the AMA should focus efforts on modernizing the fraud and
51 abuse laws to address the changing realities of the health care delivery and payment system. The

1 Anti-Kickback Statute was passed in 1972, Stark (physician self-referral law) in 1989. Significant
2 changes in health care payment and delivery have occurred since the enactment of these laws. For
3 example, PBMs did not exist, or were at least not as pervasive, when these laws were created.
4 Numerous initiatives are attempting to align payment and coordinate care to improve the quality
5 and value of care delivered. The delivery of care is going through a digital transformation with
6 innovative technology. However, the fraud and abuse laws have not commensurably changed.

7
8 The fraud and abuse laws were enacted during a time when fee-for-service, which pays for services
9 on a piecemeal basis, was blamed for rising costs. The policy reasoning behind the fraud and abuse
10 laws is to act as a deterrent against overutilization, inappropriate patient steering, and compromised
11 medical judgment with heavy civil and criminal penalties, such as treble damages, exclusion from
12 participation in federal health care programs, and potential jail time.

13
14 The health care system has evolved since the creation of these laws, and the Council believes that
15 they need to be updated to reflect changing business practices and technologies in the health care
16 industry.

17 18 RECOMMENDATIONS

19
20 The Council on Medical Service recommends that the following be adopted in lieu of Resolution
21 252-A-18, and the remainder of the report be filed:

- 22
23 1. That our American Medical Association (AMA) reaffirm Policy H-125.986 supporting
24 efforts to ensure that reimbursement policies established by pharmaceutical benefit
25 managers (PBMs) are based on medical need; these policies include, but are not limited to,
26 prior authorization, formularies, and tiers for compounded medications (Reaffirm HOD
27 Policy)
- 28
29 2. That our AMA reaffirm Policy H-110.992 stating that the AMA will monitor the
30 relationships between PBMs and the pharmaceutical industry and will strongly discourage
31 arrangements that could cause a negative impact on the cost or availability of essential
32 drugs. (Reaffirm HOD Policy)
- 33
34 3. That our AMA reaffirm Policy H-100.956 calling for collaboration with medical specialty
35 partners in identifying and supporting legislative remedies to allow for more reasonable
36 and sustainable payment rates for prescription drugs (Reaffirm HOD Policy)
- 37
38 4. That our AMA renew efforts urging the federal government to support greater public
39 transparency and accountability efforts involving the contracting mechanisms and funding
40 structures subject to the Group Purchasing Organization and PBMs anti-kickback safe
41 harbor, including the potential impact on drug pricing and drug shortages. (New HOD
42 Policy)
- 43
44 5. That our AMA support efforts to update and modernize the fraud and abuse laws and
45 regulations to address changes in the health care delivery and payment systems including
46 the potential impact on drug pricing and drug shortages. (New HOD Policy)
- 47
48 6. That our AMA, via a letter, immediately ask the Secretary of Health and Human Services
49 (HHS) and other appropriate stakeholders to request the HHS Office of the Inspector
50 General to examine the supply chain of pharmaceuticals, pharmacy benefit managers, Safe
51 Harbor laws and regulations, and expeditiously make recommendations to make

1 prescription drugs more accessible and affordable to patients with an emphasis on
2 examining the governing contracts for drugs in short supply and/or that are exceedingly
3 expensive to ensure compliance with all the safe harbor provisions. (Directive to Take
4 Action)

Fiscal Note: Less than \$500

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- ¹ Qiaohai Hu, Leroy B. Schwarz & Nelson A. Uhan, *The Impact of Group Purchasing Organizations on Healthcare-Produce Supply Chains*, Journal of Manufacturing & Service Operations Management (Dec. 2012), <https://pubsonline.informs.org/doi/abs/10.1287/msom.1110.0355>.
- ² AMA, *Practice Discounts*, <https://www.ama-assn.org/ama-member-benefits/practice-member-benefits/practice-discounts>
- ³ Henry Schein Medical, *AMA Medical Supply Buying Program*, <https://www.henryschein.com/us-en/medical/about-henry-schein-medical/partnerships-associations/ama.aspx>.
- ⁴ U.S. Government Accountability Office, *Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices*, GAO010-738, (Aug. 2010).
- ⁵ Section 1128B(b) of the Social Security Act (42 U.S.C. 1320a-7b(b)).
- ⁶ Medicare and Medicaid Patient and Program Protection Act of 1987, 101 Stat. 680, 697, P.L. 100-93 § 14 (Aug. 18, 1987).
- ⁷ Omnibus Budget Reconciliation Act of 1986, 100 Stat. 1874, 2016, P.L. 99-509, § 9321 (Oct. 21, 1986). While many articles and documents state that the statutory exception was created in 1987 by the Medicare and Medicaid Patient and Program Protection Act of 1987, the statutory exception was created in 1986.
- ⁸ H.R. Rep. No. 99-727, at 73 (1986), *reprinted in* 1986 U.S.C.C.A.N. 3607, 3663.
- ⁹ 56 Fed. Reg. 35952, 35982 (July 29, 1991).
- ¹⁰ Social Security Act § 1128B(b)(3)(A).
- ¹¹ H.R. Report No. 95-393(II), at 53, *reprinted in* 1977 U.S.C.C.A.N. 3039, 3056. (“In fact, the committee would encourage providers to seek discounts as a good business practice which results in savings to Medicare and Medicaid program costs.”).
- ¹² 42 CFR § 1001.952(h).
- ¹³ Medicare rules generally require providers to offset purchase discounts, allowances, and refunds against expenses on their Medicare cost reports. In 2005, OIG reviewed 21 GPO members, and found that they did not fully account for net revenue distributions on their Medicare cost reports. There was considerable variation among the GPOs, with members of one GPO offsetting 92 percent of the distributions, members of another offsetting only 54 percent. In total, 22 percent of net revenue distributions were not offset. OIG, *Health Care Fraud and Abuse Control Program Annual Report for FY 2005*, (Aug. 2006), <https://oig.hhs.gov/publications/docs/hcfac/hcfacreport2005.pdf>.
- ¹⁴ 56 Fed. Reg. 35952, 35953 (July 29, 1991).
- ¹⁵ 42 CFR § 1001.952(d).
- ¹⁶ HHS OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers* (Apr. 2003), <https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf>.
- ¹⁷ SSA § 1150A (42 U.S.C. § 1320b-23). In relevant part, the regulations requires each entity that provides PBM services to provide to the Part D sponsor and for each part D sponsor to provide to CMS the aggregate amount and type of rebates, discounts, or price concessions (excluding bona fide service fees as defined in §423.501) that the PBM negotiates that are attributable to patient utilization under the plan and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed. 42 C.F.R. § 423.514(d).
- ¹⁸ Based off of AMA staff interviews with trade associations and private practice attorneys who represent both sides of an arrangement.
- ¹⁹ 84 Fed. Reg. 2340 (Feb. 6, 2019)
- ²⁰ *Id.*
- ²¹ Based off of AMA staff interviews with trade associations and private practice attorneys who represent both sides of an arrangement.
- ²² U.S. Department of Justice and the Federal Trade Commission, *Statements of Antitrust Enforcement Policy in Health Care*, (Aug. 1996), pp. 53-60, https://www.ftc.gov/sites/default/files/attachments/competition-policy-guidance/statements_of_antitrust_enforcement_policy_in_health_care_august_1996.pdf.
- ²³ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation, *Economic Analysis of the Causes of Drug Shortages* (Oct. 2011), p. 4 <https://aspe.hhs.gov/system/files/pdf/108986/ib.pdf>.

- ²⁴ Kelly Gooch, *4 of the Largest GPOs 2017* (Feb 2017) <https://www.beckershospitalreview.com/finance/4-of-the-largest-gpos-2017.html>.
- ²⁵ *Southeast Missouri Hosp. v. C.R. Bard, Inc.*, 642 F. 3d 608 (2011).
- ²⁶ Q. Hu & L. Schwarz, *Controversial Role of GPOs in Healthcare-Product Supply Chains*, Production and Operations Management (2010).
- ²⁷ National Pharmaceutical Council, *Toward Better Value*, (2017), <https://www.drugchannels.net/2017/11/if-employers-are-so-unhappy-with-their.html>.
- ²⁸ Physicians Against Drug Shortages, Letter to the Food and Drug Administration, *Food and Drug Administration Drug Shortages Task Force and Strategic Plan* (Mar. 12, 2013).
- ²⁹ GAO, *Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability* (Feb. 2014), available at <https://www.gao.gov/assets/670/660785.pdf>.
- ³⁰ Independent Physicians for Patient Independence, Click and Comment to End Killer GPO/PBM Kickbacks, (Oct. 14, 2018), available at <https://ip4pi.wordpress.com/2018/10/14/click-and-comment-to-end-killer-gpo-pbm-kickbacks/>.
- ³¹ FDA, *Frequently Asked Questions on Patents and Exclusivity*, May 2, 2018, available at <https://www.fda.gov/drugs/developmentapprovalprocess/ucm079031.htm>.
- ³² Government Accountability Office, *Group Purchasing Organizations: Funding Structure has Potential Implications for Medicare Costs* (GA)-15-13) (Nov. 2014).
- ³³ Q. Hu & L. Schwarz, *Controversial Role of GPOs in Healthcare-Product Supply Chains*, Production and Operations Management (2010). This study used a Hotelling model which assumes a continuum of identical providers and two manufacturers.
- ³⁴ Q. Hu & L. Schwarz, *The Impact of Group Purchasing Organizations on Healthcare-Product Supply Chains*, Purdue University (2011).
- ³⁵ E.g., Bloomberg BNA, *Health Care Program Compliance, Personal Services and Management Agreements*, chap. 1415 (2012) (“If business realities preclude meeting all of the requirements, then meeting as many of the requirements as possible will increase the chances that the arrangement will be viewed as non-abusive, as long as there is no underlying purpose to induce or reward referrals of business reimbursed under federal health care programs.”).