HSCA
HEALTHCARE SUPPLY CHAIN ASSOCIATION
Innovators in Evidence-Based Sourcing

June 25, 2012

Diana L. Moss
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2919 Ellicott Street, N.W.
Washington, DC | 20008

Dear Dr. Moss:

Thank you for taking the time to talk with us earlier this week about your paper, "Healthcare Intermediaries: Competition and Healthcare Policy at Loggerheads?" As we indicated during our call, we are writing primarily with regard to those sections of your paper addressing issues relating to Group Purchasing Organizations ("GPO"), of the type our association represents.

While you indicated during our call that it was not your intention to reach firm conclusions and recommendations, but only to raise issues for further study, we are concerned that the final section of your paper, entitled "Conclusions and Policy Recommendations" could be misunderstood to be offering conclusions and recommendations, even if that was not your intention. We are writing, therefore, to express our strong disagreement with some of the conclusions and recommendations relating to GPOs set forth in that section of your paper, and to urge you to consider withdrawing or revising your report to take account of our concerns.

1. On p. 23, in point 3, you suggest that *Statement 7* of the 1996 DOJ/FTC STATEMENTS OF ANTITRUST ENFORCEMENT POLICY IN HEALTHCARE "should be revised to be neutral with respect to the procompetitive effects of group purchasing organizations and more consistent with general antitrust analysis of monopolization and coordinated interaction." Your paper does not identify what revisions you would like to see, but our view is that *Statement 7* is already fully consistent with the applicable antitrust principles. As the Supreme Court recognized in *Northwest Wholesale Stationers*, group purchasing arrangements generally serve "to increase economic efficiency and render markets more, rather than less, competitive," and are likely to have anticompetitive effects only when "the cooperative possesses market power or unique access to a business element necessary for effective competition."[1] Consistent with these principles, *Statement 7* creates a safe harbor for GPOs that account for less than 35 percent of purchases of any given product, and provides that the conduct of GPOs falling outside this safe harbor will be analyzed under the antitrust rule of reason, which enables the courts to evaluate on a case-by-case basis whether the particular conduct in question is, on balance, procompetitive or anticompetitive. We see nothing in your paper that would support moving away from these sound, neutral principles.

2. On p. 23, in point 5, you suggest that "Congress should repeal the anti-kickback safe harbor." This suggestion appears to be based on your view that allowing GPOs to recover their

[1] *See Northwest Wholesale Stationers v. Pacific Stationery & Printing Co.*, 472 U.S. 284, 295-96 (1985).

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administrative costs through fees paid by suppliers creates a principal-agent problem and may potentially foreclose smaller medical device and pharmaceutical manufacturers from the market. As we explained during our call, it is not unusual for intermediaries to receive some or all of their compensation from sellers rather than buyers, and there are many sound economic reasons for structuring compensation arrangements in this way. As we reminded you, former New York Attorney General Elliot Spitzer raised similar concerns over the long-standing practice in the insurance industry of insurers brokers receiving compensation from insurers in the form of direct and contingent commissions, in addition to or in lieu of fees paid from their client insureds. This led many state insurance commissions to review this long-standing business practice. Every state insurance commission that conducted such a review ultimately concluded that brokers should be allowed to continue to receive compensation in the form of direct and contingent commissions from insurers so long as those compensation arrangements were fully disclosed to their clients.

This is the same conclusion Congress reached when it established the exemption to the anti-kickback statute for the administrative fees paid by medical goods suppliers to GPOs. Congress concluded that the type of principal-agent issues you raise with respect to GPO administrative fees, which had been in existence for decades, did not justify prohibiting such payments, but could be addressed by requiring that these arrangements be in writing and by giving HHS the authority to require that the amounts of the fees received be disclosed to the extent HHS deemed necessary. HHS has exercised this authority by requiring that any GPO that receives administrative fees in excess of 3 percent of the purchases made through it must disclose the amount of the fees it receives to the entity making those purchases and, upon request, to HHS itself.

As your paper acknowledges, in August 2010, GAO issued a report examining the amount of the administrative fees received by six of the largest GPOs.[2] It found that the average contract administrative fees paid by vendors in 2008 to these GPOs, weighted by purchasing volume, ranged from 1.22 percent of customer purchases to 2.25 percent, and that only two of the GPOs reported receiving fees in excess of the 3 percent HHS threshold for disclosure of the amounts received.[3] An earlier 2005 HHS audit of administrative fees received by six of the largest GPOs found that of the fees received by these GPOs in excess of their administrative costs, roughly two-thirds were distributed to the members on whose behalf the GPO purchased supplies, with the remainder being used to provide reserves and venture capital for the provision of additional services.[4] The distribution of the monies received by GPOs through administrative fees to their

[2] U.S. Government Accountability Office, Group Purchasing Organizations: Services Provided to Customers and Initiatives Regarding Their Business Practices (GAO-10-738) 4 (August 2010), available at http://www.gao.gov/assets/310/308830.pdf.
[3] *Id.* at 11-12.
[4] Office of Inspector General, Dep't of Health & Human Serv., *Review of Revenue from Vendors at Three Group Purchasing Organizations and Their Members,* A-05-03-00074 (Jan. 2005).

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members further mitigates any potential principal-agent problem such fees might otherwise create.

Based on these facts, we believe your suggestion at various points in your paper that these administrative fees create what you call "perverse incentives" is unfounded. The assertion that GPOs charge higher prices to increase their administrative fees and that hospitals would pay higher prices for a product so as to benefit the GPO is, frankly, absurd. In the highly competitive healthcare supply marketplace, no GPO would survive if it did not deliver real value. We, therefore, see no reason for Congress to repeal the exemption from the anti-kickback statute for GPO administrative fees.

3. On p. 23, in point 6, you suggest that industry self-regulation is "an ineffective method of policing the underlying features (e.g., administrative fee levels) that promote potentially exclusionary practices that can harm competition and consumers." As just discussed, we disagree with your underlying premise that administrative fees promote exclusionary practices. Your paper cites no facts that would suggest that GPOs generally engage in exclusionary practices. In fact, as the GAO has reported, the Justice Department reviewed complaints of exclusionary business conduct by GPOs filed by certain medical device manufacturers at the beginning of the Obama Administrative in 2009 and declined even to open an investigation because the complainants were unable to provide any evidence to support their complaints.[5]

That same GAO report found that through the Health Group Purchasing Industry Initiative ("HGPII"), GPOs have continued to upgrade and improve their mechanisms for industry self-regulation. These improvements include allowing vendors who are dissatisfied with the results of HGPII's own formal grievance process to have its complaint reviewed by a third party provided by the American Arbitration Association. So far as we can tell from your paper, it does not appear that you have undertaken any independent review of whether GPO industry self-regulation is working effectively and that your suggestion that it is ineffective is, therefore, completely unsubstantiated.

4. At several points in your paper, you allege that the incentives inherent in the current GPO fee structure are misaligned. For example, on p. 15, you state:

> "The perverse incentives that underlie the GPO business model may help clarify the role of group buyers in drug shortages. Under the current system of compensation, GPOs are paid by vendors, rather than by parties to the agreement. An arrangement whereby a manufacturer, rather than the principal (i.e., buying group member), pays the agent (i.e., buying group) raises the classic

[5] U.S. Governmental Accountability Office, Group Purchasing Organizations: Federal Oversight and Self-Regulation (GAO-12-399R) 6 (March 30, 2012), available at http://www.gao.gov/assets/590/589778.pdf.

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> principal-agent problem. This is similar to the compensation structure for credit rating agencies, under which the agencies are paid by the firms they rate rather than by the users of their reports."

This analysis is incorrect, perhaps because it relies on the misunderstanding of how the GPO industry works. For example, on p. 3 you state, "A GPO purchases drugs, medical devices, and supplies on behalf of member hospitals." This is simply not the case. GPOs do not purchase anything. Nor do they have the ability to compel their members to buy any particular product.

The transaction at the core of the issue is the purchase by hospitals of products from manufacturers and distributors. In those transactions, the hospital makes the purchasing decision, they pay for the product, they take possession of the product, and they use the product.

While the GPO fees are paid by the manufacturer, those fees are only paid if the underlying transaction takes place at the GPO negotiated price. The fees themselves are not the core transaction; the purchase by the hospital of the product is. If the hospital does not buy the good or service, or if it buys the good or service "off contract", or if it buys the product at a price negotiated by another GPO, then there is no fee. Thus, the incentive for the GPO is fully aligned with the hospital -- negotiate the best price to maximize the hospitals incentive to purchase products at the GPO negotiated price.

Apart from the conclusions and recommendations section of your paper, we are also concerned about suggestions earlier in your paper that GPOs may have contributed to the drug shortages the United States experienced in 2010, especially for intravenously-administered generic oncology drugs. As your paper acknowledges, the causes of these shortages have been studied both by the FDA and HHS, neither of which found anything to suggest that GPO contracting practices contributed to those shortages. More recently, the Committee on Oversight and Government Reform of the U.S. House of Representatives released a staff report just last week, reviewing the causes of these drug shortages. Its report concluded that the primary cause of the shortages was FDA's action in simultaneously requiring remediation efforts at a number of manufacturing facilities producing those drugs. FDA's action effectively shut down 30 percent of the total manufacturing capacity at four of the country's largest producers of generic injectable medications.[6] While the report found that another contributing factor might be the growing concentration in the market for generic injectable medications, resulting from pressure to hold down the costs of healthcare generally, the Committee staff found that most of that pressure had come from Medicare, which limits the amount it will reimburse providers for injectable drugs, not from GPOs. Again, we are concerned that your paper will unfairly leave readers with the impression that GPOs are somehow responsible for a public health problem when the facts are otherwise.

[6] U.S. House of Rep., Committee on Oversight & Gov't Reform, Staff Report on FDA's Contribution to the Drug Shortage Crisis, 112th Cong., 2d Sess (June 15, 2012).

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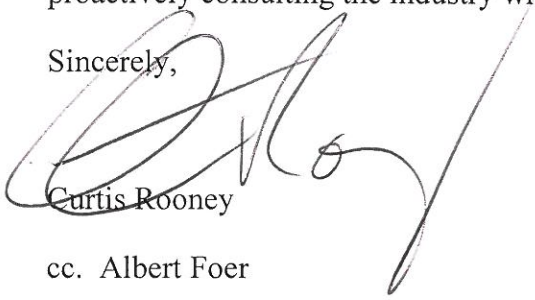
Again, we appreciate the opportunity to comment on your paper. We hope you find our comments helpful, and that you will consider either withdrawing or substantially revising your paper to take account of our concerns. In the future, we urge you to use HSCA as a resource before you publish a paper focusing on the industry. While we might not agree on everything, proactively consulting the industry will help lead to a more constructive dialogue.

Sincerely,



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