AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT, CEO

ama-assn.org
t (312) 464-5000

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The Honorable Alex Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

The Honorable Joanne M. Chiedi
Acting Inspector General
Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Azar and Acting Inspector General Chiedi:

On behalf of our physician and medical student members, the American Medical Association (AMA) requests that the Office of Inspector General (OIG) examine the supply chain of pharmaceuticals, pharmacy benefit managers (PBMs), and the fraud and abuse laws. Prescription drug prices continue to present serious barriers to medically necessary treatments and undermine the fiscal sustainability of the health care system. Thus, this examination should include studying the governing contracts for medication in shortage or that are exceedingly expensive. Moreover, based upon any relevant findings, we request that OIG make additional recommendations to make prescription medication more accessible and affordable to patients.

The AMA supports policy, legislation, and regulation that increases transparency along the pharmaceutical supply chain. Knowledge of the entire supply chain, including contracting mechanisms and funding structures between manufacturers, suppliers, and distributors, can provide valuable information for needed evaluation and analysis regarding how these mechanisms can contribute to high medication pricing and shortages. For example, PBM contracting mechanisms may have an impact on choice and competition. Complaints about the PBM contracting process include employers wanting an alternative to a rebate-driven approach to managing costs, PBMs lacking transparency about how they generate revenue, contracts being complicated and including clauses that benefit the PBM at the expense of the employer or patient, and rebates contributing to misaligned incentives that put PBM interests before patients or employers (no fiduciary obligation).[1] Accordingly, OIG should examine contracting mechanisms and funding structures for prescription drugs in short supply or that are exceedingly expensive and make appropriate recommendations.

We also believe that OIG should promote greater transparency and accountability efforts regarding the actions covered by the Group Purchasing Organization (GPO) anti-kickback safe harbor. In 2014, GAO recommended that CMS should determine whether hospitals are appropriately reporting administrative fee revenues on their Medicare cost reports and take steps to address any underreporting that may be found. In response, CMS issued a Technical Direction Letter to the Medicare Administrative Contractors (MAC) in 2015 adding steps to the desk review program. Specifically, CMS directed MACs to verify that

[1] National Pharmaceutical Council, *Toward Better Value*, (2017), https://www.drugchannels.net/2017/11/if-employers-are-so-unhappy-with-their.html.

GPO revenues have been offset where appropriate to mitigate any risk to the Medicare program. However, nothing has been publicly released based off of these desk reviews. Moreover, HHS has the capability to request records from GPOs and PBMs availing themselves to this safe harbor the amount received from each vendor with respect to purchases made by or on behalf of the GPO and PBM customers. Yet, the AMA is unaware of any requests or public reports based off any requests since the GAO report. Given the push for greater price and cost transparency and the lack of recent data related to GPOs and PBMs, the AMA recommends that the OIG renew efforts to support greater public transparency and accountability efforts involving the contracting mechanisms and funding structures subject to the GPO anti-kickback safe harbor.

Additionally, the AMA believes that the OIG needs to eliminate the application of the GPO regulatory safe harbor to PBMs. The only formal pronouncement on PBMs and the application of the GPO regulatory safe harbor is found in sub-regulatory guidance: Compliance Program Guidance for Pharmaceutical Manufacturers issued in 2003.[2] "Any rebates or other payments by drug manufacturers to PBMs that are based on the PBM's customers' purchases potentially implicate the anti-kickback statute. Protection is available by structuring such arrangements to fit in the GPO safe harbor."[3] Through this language, the OIG potentially extended the GPO regulatory safe harbor (which is meant to cover administrative fees) to include "any rebates or other payments."[4]

The AMA appreciates the Department's focus on this important issue and efforts towards ensuring the affordability of prescription drugs for all Americans. With medication prices reaching new extremes, every possible effort must be made to ensure that patients can afford the treatments they need most. We look forward to working with you to take meaningful steps towards ensuring the affordability of prescription drugs for our patients. If you would like to discuss further or have any questions, please contact Shannon Curtis, Assistant Director of Federal Affairs at Shannon.Curtis@ama-assn.org or 202-789-8510.

Sincerely,

James L. Madara, MD

[2] HHS OIG, *Compliance Program Guidance for Pharmaceutical Manufacturers* (Apr. 2003), p. 24-25, https://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf.
[3] *Id.*
[4] *Id.*