

Physicians Against Drug Shortages (PADS)

February 16, 2021

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Agency: Health & Human Services Office of Inspector General

Comments in response to solicitation of “Proposals and recommendations for developing new, or modifying existing, safe harbor provisions under section 1128B(b) of the Social Security Act (the Act), the Federal anti-kickback statute, as well as developing new OIG Special Fraud Alerts.”

Ms. Christi A. Grimm
Principal Deputy Inspector General
Office of the Inspector General
Department of Health & Human Services
Washington, D. C.

Dear Ms. Grimm:

On behalf of our *pro bono* patient advocacy group, I’d like to thank you for the opportunity to comment on the antikickback safe harbors for hospital group purchasing organizations (GPOs) and pharmacy benefit managers (PBMs) and to recommend modifications to the safe harbor rules and new special fraud alerts.

As I explained in my comments (attachment), we believe that the AKS safe harbors for GPOs and PBMs are the most harmful healthcare statutes ever enacted. Overwhelming independent documentation shows that GPOs have undermined competition and innovation in America’s health care supply chain, thereby in-

flating healthcare supply costs by least 30%, or an estimated \$100 billion annually, and causing chronic shortages of generic drugs, and more recently, lifesaving personal protection equipment (PPE) and supplies. Similarly, PBMs have inflated prices of drugs sold to individuals by an estimated \$130 billion annually,

We understand, of course, that only Congress can repeal these safe harbors. Since that is unlikely to happen anytime soon, we've recommended rule modifications and special fraud alerts that we believe would at least mitigate the harm these anticompetitive abuses have caused patients, clinicians and taxpayers. They would improve 1) the quality of health care services; 2) decrease the cost to federal health care programs; and 3) increase access to health care services, among other benefits. We urge you to consider them very seriously. Feel free to contact me if you have any questions.

Respectfully submitted,

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