

February 26, 2018

The Honorable Daniel R. Levinson  
Inspector General, Department of Health and Human Services  
Cohen Building, Room 5541C  
330 Independence Ave. SW  
Washington, DC 20201

***RE: Solicitation of New Safe Harbors and Special Fraud Alerts  
[OIG-127-N]***

Mr. Levinson:

We, the undersigned organizations, appreciate the opportunity to provide input on modifying and/or establishing safe harbor provisions under the Federal Anti-Kickback Statute. During the past decade, payment models for the delivery of health care have undergone a shift from focusing on volume to focusing on value. Current laws and regulations present challenges for the development and implementation of these agreements. Specifically, lack of clarity about treatment of these arrangements under the Federal Anti-Kickback Statute poses a significant barrier. The recommendations included in this letter are based upon consensus recommendations of an Academy of Managed Care Pharmacy (AMCP) Partnership Forum, *Advancing Value-Based Contracting (VBC)*, held in June 2017. The forum included nearly 40 thought leaders representing diverse health care sectors, including health plans, integrated delivery systems, pharmacy benefit managers, clinical practice, and biopharmaceutical and laboratory companies.<sup>1</sup>

We support establishing a safe harbor provision that would encourage the development of additional VBCs for the Medicare and Medicaid populations. VBCs have emerged as a mechanism that payers may use to better align their contracting structures with broader changes in the health care system. The participants in AMCP's Partnership Forum established a consensus definition that "value-based contracts" means a written contractual agreement in which the payment terms for medication(s) or other health care technologies are tied to agreed-upon clinical circumstances, patient outcomes, or measures.<sup>2</sup>

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<sup>1</sup> Academy of Managed Care Pharmacy Partnership Forum: Advancing Value-Based Contracting. JMCP 2017 Nov; 23(11), pp. 1096-1102. Accessible here: [www.jmcp.org/doi/pdf/10.18553/jmcp.2017.17342](http://www.jmcp.org/doi/pdf/10.18553/jmcp.2017.17342).

<sup>2</sup> *Ibid.*

The Federal Anti-Kickback Statute makes it a criminal offense to knowingly and willfully provide something of value with the intent to induce the purchase of items or services payable by a federal health care program. Thus far, to the extent that biopharmaceutical manufacturers and population health decision makers interested in entering a VBC have questions about the application of the Federal Anti-Kickback Statute, the only available option is to seek an advisory opinion from the Office of the Inspector General, which is a lengthy process. These delays can mitigate the benefits of such programs. Given that some elements of VBCs share common characteristics and pose low risk of fraud and abuse, we believe VBCs to be suitable for development of a regulatory safe harbor.

Establishing a safe harbor for VBCs would help to remove the regulatory uncertainty that currently stands as an obstacle to broader adoption of VBCs. The safe harbor should include a wide range of services to not only address the current construct of VBCs, but also to encourage best practices for future innovation as new advancements in health care are introduced. Examples include but are not limited to: interventions that improve medication utilization to promote better outcomes, mobile health products provided to the patient, and analytics related to the potential impact on outcomes and costs for certain patient populations. As another solution, the OIG could issue an opinion or guidance that VBCs do not invoke the Federal Anti-Kickback Statute or clarification of the requirements of the discount safe harbor that would help address this barrier.

We appreciate the opportunity to submit these comments, and we look forward to working collaboratively with your office to reduce regulatory barriers to innovation. If you have questions or require further information on this issue, please contact Mary Jo Carden, Vice President of Government and Pharmacy Affairs at the Academy of Managed Care Pharmacy at 703-684-2603 or [mcarden@amcp.org](mailto:mcarden@amcp.org).

Sincerely,

Academy of Managed Care Pharmacy  
America's Physician Groups  
Council for Affordable Health Coverage  
Eli Lilly and Company  
EMD Serono  
Harvard Pilgrim Health Care  
Healthcare Leadership Council  
Merck  
Novo Nordisk  
Pharmaceutical Research and Manufacturers of America  
Prime Therapeutics  
Teva Pharmaceuticals