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December 31, 2019

Joanne M. Chiedi
Acting Inspector General
Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201
Attn: OIG–0936-AA10-P

Re: Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements [OIG-0036-AA10-P]

Dear Acting Inspector General Chiedi:

The Academy of Managed Care Pharmacy (AMCP) thanks the Office of Inspector General (OIG) for the opportunity to provide written comments regarding the new proposed rulemaking on *"Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements"* published in the *Federal Register* on October 17, 2019. AMCP appreciates the Department of Health and Human Services (HHS) and OIG's continued work on the Regulatory Sprint to Coordinated Care initiative ("Regulatory Sprint") and recognition of the barriers imposed by the Federal Anti-Kickback Statute (AKS) on the transition to value-based care.

AMCP is the nation's leading professional association dedicated to increasing patient access to affordable medicines, improving health outcomes and ensuring the wise use of health care dollars. Through evidence- and value-based strategies and practices, the Academy's 8,000 pharmacists, physicians, nurses and other practitioners manage medication therapies for the 270 million Americans served by health plans, pharmacy benefit management firms, emerging care models and government.

OIG has taken the first steps toward much needed reform of the AKS by proposing to modify certain existing safe harbors and add three proposed new safe harbors that foster better coordinated care and patient management. However, AMCP is concerned that the proposed safe harbors will exclude key stakeholders from protection and limit the ability of covered stakeholders to provide meaningful value-based care. Specifically, AMCP is concerned that OIG's proposal "expressly excludes" pharmaceutical manufacturers as Value-Based Enterprise (VBE) participants that could collaborate to achieve value-based purposes and participate in arrangements eligible for safe harbor protection. The exclusion of pharmaceutical manufactures could lead to the hampering of data sharing between

payers and biopharmaceutical companies to facilitate better decision-making related to medication selections for formularies and pharmacy benefits for populations.

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 AKS poses a significant barrier. To address current barriers and to allow for better care coordination and information sharing among clinical providers, treatment facilities, and patients, AMCP strongly supports establishing a safe harbor provision that would encourage the development of additional Value Based Contracts (VBCs).

This recommendation is based upon consensus recommendations of an 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.[1] Forum participants 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.[2]

The AKS 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 heath decision makers interested in entering a VBC have questions about the application of the AKS, the only available option is to seek an advisory opinion from the OIG, 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 AKS or clarification of the requirements of the discount safe harbor that would help address this barrier.

AMCP also strongly encourages OIG to stand by its intent to include pharmacy benefit managers (PBMs) and pharmacists as VBE participants. PBMs should be included in these arrangements to promote value-based care recognizing the important role they play in supporting all of the value-

[1] Academy of Managed Care Pharmacy Partnership Forum: Advancing Value-Based Contracting. Journal of Managed Care & Specialty Phamacy. 2017; 23(11):1096-1102. Available at: www.jmcp.org/doi/pdf/10.18553/jmcp.2017.17342. Accessed on December 18, 2019.
[2] Ibid.

based purposes described in OIG's proposal. Additionally, pharmacists' inclusion will allow them to work with physicians and other healthcare providers to optimize medication therapy and deliver ideal patient-centered care. Through the delivery of direct patient care, pharmacists, in collaboration with physicians, nurses, patients, and other healthcare providers can offer ongoing, comprehensive assessment and management of drug therapy that is patient-centered, improves quality of care, produces desired patient outcomes, and reduces overall costs of care. The inclusion of pharmacists in the definition of a VBE participant will enhance their ability to work as part of healthcare teams to address primary healthcare needs and increase the potential of pharmacists to provide these services with fewer barriers.

AMCP appreciates the opportunity to comment on this important topic and we look forward to working collaboratively on these issues with OIG to reduce care coordination barriers. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703-684-2600 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell. RPh, CAE
Chief Executive Officer