



April 2, 2021

Ms. Christi A. Grimm
Principal Deputy Inspector General
Office of the Inspector General
Department of Health and Human Services
330 Independence Avenue, S.W.
Washington, D.C. 20201

Re: Anti-Kickback Statute Safe Harbors

Dear Principal Deputy Inspector General Grimm:

The Academy of Managed Care Pharmacy (AMCP) thanks the Office of the Inspector General (OIG) for the opportunity to provide input on the development of additional safe harbors of the Federal Anti-Kickback Statute (AKS). We appreciate the opportunity to leverage our members' expertise in offering this feedback.

AMCP is the professional association leading the way to help patients get the medications they need at a cost they can afford. AMCP's diverse membership of pharmacists, physicians, nurses, biopharmaceutical professionals, and other stakeholders leverage their specialized expertise in clinical evidence and economics to optimize medication benefit design and population health management and help patients access cost-effective and safe medications and other drug therapies. AMCP members improve the lives of nearly 300 million Americans served by private and public health plans, pharmacy benefit management firms, and emerging care models.

AMCP appreciates OIG's recent efforts to update the AKS to better foster coordinated care and patient management, including its 2020 rule that modernized the AKS by adding new safe harbors that aimed to support innovative methods of care management and novel payment arrangements. However, AMCP is concerned that the rule excludes key stakeholders from these safe harbor protections, which will limit the ability of covered stakeholders to provide meaningful value-based care. In particular, we are concerned that the rule expressly excludes pharmacy benefit managers (PBMs) and pharmaceutical manufacturers from being covered as Value-Based Enterprise (VBE) participants that can collaborate with other stakeholders to achieve value-based purposes and participate in arrangements eligible for the new safe harbor protections.

AMCP was disappointed by OIG's decision to exclude PBMs from the new value-based care safe harbor. PBMs are participants in value-based arrangements for prescription drugs and should be included the safe harbor protections to recognize their role in supporting the value-based purposes described in the rule. Similarly, pharmaceutical manufacturers participate in value-based agreements for their products and should be afforded AKS safe-harbor protections when engaging with other health care stakeholders in this manner.

Over the past decade, health care payment models have undertaken a shift from focusing on volume to focusing on value. Unfortunately, current laws and regulations can serve as barriers to the development and implementation of value-based arrangements. Specifically, the lack of clarity about the treatment of such arrangements under the AKS poses a considerable challenge to their increased use. In the case of arrangements including PBMs and pharmaceutical manufacturers, the lack of clarity can hamper data sharing between manufacturers and payers and the PBMs they contract with that could facilitate better decision-making related to formulary development and pharmacy benefit design. To address these barriers and promote better care coordination and information sharing, AMCP supports the inclusion of PBMs and pharmaceutical manufacturers in the new value-based care safe harbors as well as the creation of additional value-based contract safe harbors.

AMCP's recommendation to include these stakeholders and to create additional safe harbors for value-based contracts is informed by a 2017 AMCP Partnership Forum titled "Advancing Value-Based Contracting" which brought together nearly 40 thought leaders representing diverse health care sectors including payers, PBMs, manufacturers, clinical providers, and integrated delivery systems, among others. Forum participants agreed on a consensus definition for value-based contracts and agreed that the AKS can serve as a barrier to their increase adoption.¹ Currently, when potential participants in a value-based contract have questions about the application of the AKS to an arrangement, their only option is to seek an advisory opinion from the OIG – a lengthy process which may lead to delays that outweigh the benefits of such value-based arrangements. A safe harbor for these contracts, along with the inclusion of PBMs and manufacturers in the recently finalized value-based safe harbors, would mitigate these delays, and help advance value-based contracting for pharmaceuticals.

Establishing a regulatory safe harbor for value-based contracts would remove regulatory uncertainty and likely would pose a low risk of fraud or abuse. Many value-based contracts have similar common elements that make them suitable for an AKS safe harbor. Such a safe harbor should include a wide range of services to not only address the current construction of many value-based contracts, but to also encourage best practices for future innovation as new advancements in health care are introduced. Examples could include interventions that improve medication utilization to promote better outcomes, mobile health products provided to a patient, and analytics related to the potential impact on outcomes and costs for certain population populations. As an alternative to the creation of new safe harbors, OIG could issue an opinion or new guidance stating that value-based contracts do not invoke the AKS. These actions would help to remove the barriers and uncertainty that currently stand as obstacles to broader adoption of value-based contracts.

AMCP appreciates the opportunity to provide input on the development of new Federal AKS safe harbors. We are committed to being a valuable resource to OIG on improving access to prescription drugs at lower costs and reducing costs in the health care system. If you have any questions regarding AMCP's comments or would like further information, please contact Carrie Monks, AMCP Director of Regulatory Affairs, at 703-684-2637 or cmonks@amcp.org.

¹ See: <https://www.jmcp.org/doi/full/10.18553/jmcp.2017.17342>

Sincerely,

A handwritten signature in black ink, appearing to read "S. Cantrell". The signature is fluid and cursive, with a long horizontal stroke extending from the end.

Susan A. Cantrell, RPh, CAE

Chief Executive Officer