



**Association of  
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*Submitted electronically*

October 26, 2018

Daniel R. Levinson  
Inspector General  
Department of Health and Human Services  
330 Independence Avenue, SW, Room 5250  
Washington, DC 20201  
**RE: OIG-0803-N**

***Re: OIG Request for Information Regarding the Antikickback Statute and Beneficiary Inducement CMP***

Dear Mr. Levinson:

The Association of American Medical Colleges (AAMC or Association) welcomes this opportunity to comment on the Department of Health and Human Services Office of Inspector General's (OIG) Request for Information on ways to modify or add regulatory safe harbors and exceptions for the Anti-Kickback Statute and beneficiary inducement Civil Monetary Penalty (CMP) to foster arrangements that would promote care coordination and advance the delivery of value-based care while protecting against harms caused by fraud and abuse.

The AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences.

The AAMC appreciates the Department of Health and Human Services Office of Inspector General's (OIG) acknowledgment that fraud and abuse statutes may be a barrier to parties participating or considering participation in integrated delivery models, alternative payment models, and arrangements to incent improvements in outcomes and reductions in cost. The Association supports health care delivery and payment reform models that use incentives for higher-value care for patients, foster greater coordination among providers, and generally improve overall population health. Academic medical centers (AMCs) have been leaders in testing new payment models, including Medicare Shared Savings Program (MSSP) ACO

(Accountable Care Organizations), Next Generation, CPC +, Bundled Payments for Care Improvement (BPCI), Comprehensive Care for Joint Replacement, Oncology Care, and other models.

### **General Comments**

To achieve the goals of delivery system reform, there must be changes to federal laws and regulations affecting hospital-physician arrangements that were enacted many years ago, including the Physician Self-Referral Law (also known as “Stark”), the Anti-kickback law, and the Civil Monetary Penalties (CMP) Law. Since enactment of these laws, there have been major changes in health care delivery and payment, including many initiatives to align payment with quality and to improve coordination of care. Our members report that provisions in these laws, which were enacted to address issues in a fee-for-service system, present significant barriers to clinical and financial integration aimed at improving the quality of care, population health, and reducing costs.

Congress recognized that the antikickback laws were overly broad and therefore authorized the HHS Secretary to create “safe harbors” in 1987 to protect certain arrangements that are unlikely to pose risk. Congress intended for these safe harbors to be updated to reflect changes in health care delivery and payment. However, existing safe harbors remain overly prescriptive and do not address the changes in health care delivery. For example, the majority of safe harbors require that any transfer of remuneration between referral sources result in a “fair market value” exchange that is set in advance. This requirement leaves little flexibility to structure incentive payment arrangements to physicians participating in alternative payment models. For example, it is difficult to determine whether a gain-sharing payment meets fair market value because payment under these arrangements is dependent on the total savings generated by participants in the alternative payment model. Savings also depend on meeting quality benchmarks so there is no incentive to fail to provide beneficiaries with the care that they need.

The OIG and CMS have played critical roles in the development and growth of delivery and payment reforms by establishing waivers for the federal program integrity laws for specific alternative payment models, such as the shared savings Accountable Care Organization (ACO) model and the Comprehensive Care for Joint Replacement (CJR) model. However, these waivers only apply on a case-by-case basis to the specific models. While physician participation in new innovative payment and delivery models is critical for their success, many physicians are reluctant to participate in these models because they do not want to inadvertently violate federal laws that prohibit the very financial relationships necessary to achieve the clinical and financial integration necessary to be successful in reform.

The highly regulated nature of the alternative payment models guards against the possibility that patients will be denied care or will receive poor quality care. Therefore, we recommend that CMS and OIG continue to make changes and create new safe harbors and exceptions to enable financial arrangements that involve risk sharing and gain-sharing when appropriate safeguards are in place. It is critical that CMS, the OIG, and other associated agencies coordinate their efforts to allow waivers of the physician self-referral law, the civil monetary penalties and anti-

kickback laws, as appropriate to support the clinical and financial integration needed for the success of these new delivery and payment models.

Our recommendations for specific changes to the antikickback statute and civil monetary penalties, including but not limited to establishing a safe harbor for alternative payment models, are enumerated below.

### **OIG Should Establish a Safe Harbor for Value-Based Alternative Payment Models**

The AAMC recommends that a new valued based “alternative payment model” safe harbor be created to allow remuneration that is provided and received under such arrangements. These alternative payment models pose little risk of program or patient abuse and are intended to provide better quality care and greater efficiency.

The conditions set forth by the OIG and CMS that must be met to obtain a waiver from the self-referral and anti-kickback laws for providers participating in the Bundled Payment for Care Improvement (BPCI) Model, the shared savings ACO program, and the CJR model, could be used as guidance in creating this safe harbor. This safe harbor should be designed to protect models that: 1) promote accountability for quality, cost and care of patients; 2) require care management and coordination; and 3) involve investment in redesigning care processes to ensure high quality efficient care delivery.

Any remuneration that is provided and received under such a clinical integration arrangement between providers (e.g. hospitals) and physicians should be protected under this safe harbor exception as the remuneration is reasonably related to and used to achieve the objectives of clinical integration. This safe harbor should protect incentive payments, shared savings payments that are distributed from cost savings, and support provided to assist with implementation of the clinical integration arrangement (e.g. electronic health care records, data or clinical analysis tools).

This new safe harbor would allow hospitals and health systems to take steps that will improve care coordination, lower costs, and improve quality. For example, hospitals, health systems and physicians work to coordinate care as a team to achieve lower costs and higher quality. These teams need to share information about their patients to make appropriate decisions about the patient’s care. This requires maintaining systems that securely transmit information across sites of care. To achieve this coordination, hospitals may need to provide data analytic tools to community physicians to assist them in treatment decisions. In its current form, the antikickback laws make it difficult to provide such tools.

In addition, hospitals and health systems want to reward physicians who participate in the development of the care systems and adhere to pathways to achieve the best outcomes in treating their patients. In the current system, linking incentive payments to such pathways could be prohibited under the antikickback law. Also, hospitals would like to incentivize physicians to reduce unnecessary health care expenditures by encouraging them to select the most efficient and effective treatment options. Physicians can be motivated to achieve this goal by sharing in

the cost-savings achieved while still maintaining high quality. It is unclear whether some of these cost-savings financial arrangements are allowed.

### **Academic Medical Centers and Community Providers**

As new delivery models emerge, there has been an increase in relationships between academic medical centers and community physicians. At times the physicians are employed by the academic medical center, but at times they may not be. For employed physicians these new models should not pose a problem. Even when the physicians are not employed by the AMC, these relationships enable better coordination and increased access to services for the community served by the academic medical center. As these relationships develop, the academic medical centers may need to provide the community physicians with tools, such as EMRs, and data analytic tools, that enable members of the patient care team to share information and better coordinate care, improve quality, and reduce costs. As the OIG considers changes to the antikickback law, we recommend that these types of arrangements be protected.

### **OIG Should Establish a Safe Harbor for Patient Assistance that Promotes Access to Healthcare**

The healthcare system is undergoing enormous transformations in care delivery with the goal of improving care and population health. The transition from volume to value based and patient centered care requires new and changing relationships among health care providers and the patients they treat. Hospitals responsibility for their patients now extends beyond the inpatient hospital stay as increasingly they are held accountable for care provided outside of the hospital setting. Policies, such as the Medicare readmissions penalty, hold hospitals accountable for care coordination and the success of treatment post-discharge. Hospitals are engaged in population health initiatives with the goal of reducing unnecessary health care expenditures and improving health care and outcomes. Congress intended safe harbors to evolve with changes in the health system.

Providers need the flexibility to use tools that promote the health of their patients. For example, providing transportation to/from the hospital or physician's office to a patient for medically appropriate health care services enables a patient to get access to services. In addition to transportation, providers need the ability to also provide other types of support to the patient to improve their health care. Examples of ways that providers can support patients include provision of home monitoring devices, telemedicine capability, self-monitoring tools, post-discharge contacts by clinicians, and other educational resources. Providing these types of services to patients post-discharge from the hospital improves care and reduces the likelihood of the patient being readmitted to the hospital. Promoting access to care should also include nonclinical care that is reasonably related to the patient's medical care. This could include social services, dietary counseling, health coaching, provision of food, and meal preparation.

In the past, the OIG has interpreted the definition of "care" to apply only to "medically necessary" services. The OIG should also recognize that access to care includes more than "medical or clinical care", but also includes access to other services that impact health outcomes. Rather than limiting it to "medically necessary" items or services, it should include assistance

that helps to provide basic needs essential for health, such as food and shelter. The OIG has been granted discretionary authority to create Antikickback statute (AKS) safe harbors that, among other criteria, improve beneficiary access to care, and therefore we strongly recommend that the OIG exercise the authority to create this safe harbor.

Protection under the CMP statute exists for remuneration which promotes access and poses a low risk of harm for patients and federal health programs. However, this exception to the beneficiary inducements CMP, which was created by the Affordable Care Act (ACA) applies under only the CMP statute. The same protection does not exist in the antikickback laws. Therefore, we recommend the OIG establish a safe harbor to the antikickback statute for patient assistance that promotes access to health care and poses low risk of harm to patients and the federal health system.

### **Conclusion**

Given the increasing prevalence of payment programs that focus on meeting well-defined quality standards combined with requiring participants to accept more risk, and the need to, at a minimum, allow for gain-sharing with physicians and others, it is time for Congress, CMS, and the OIG to consider the many changes that should be made to various fraud and abuse laws. With the ample protections against program and patient abuse that are now, and increasingly will be, part of the Medicare program, the focus should be on simplifying and making waivers and exceptions more broadly available as an important tool to encourage wider participation.

Thank you for the opportunity to present our views. If you have any questions, please feel free to contact Gayle Lee, Director Physician Payment and Quality at 202-741-6429 or at [galee@aamc.org](mailto:galee@aamc.org) or Ivy Baer, J.D., M.P.H., Senior Director and Regulatory Counsel, at 202-828-0499 or at [ibaer@aamc.org](mailto:ibaer@aamc.org).

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski MD". The signature is fluid and cursive, with a large initial "J" and "M".

Janis M. Orlowski, MD, MACP  
Chief Health Care Officer

cc: Ivy Baer, Gayle Lee