



**Association of  
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January 27, 2016

Kim Brandt  
Chief Oversight Counsel  
United States Senate Committee on Finance  
219 Dirksen Senate Office Building  
Washington, DC 20510

Tegan Gelfand  
Professional Staff Member  
House Ways & Means Committee  
1102 Longworth House Office Building  
Washington, DC 20515

***Re: Comments on Improving the Stark law to Accommodate Delivery and Payment Reform***

Dear Ms. Brandt and Ms. Gelfand:

The Association of American Medical Colleges (AAMC) welcomes the opportunity to provide feedback to the Senate Finance Committee and House Ways and Means Committee regarding the impact of the self-referral (Stark law) on health care payment and delivery system reform, and how the law and regulations could be changed to promote development of alternative payment models. The AAMC is a not-for-profit association representing all 145 accredited U.S. medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic and scientific societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians. The AAMC strongly supports health care delivery and payment reform models that use incentives for higher-value care, foster greater coordination, and improve population health.

In January of 2015, the Secretary of DHHS set a goal of tying 30 percent of traditional, fee-for-service Medicare payments to quality or value through alternative payment models by the end of 2016 and 50 percent of payments to these models by the end of 2018. The passage of the Medicare Access and CHIP Authorization Act (MACRA) ensured that Medicare payments to physicians will move more aggressively in that direction. MACRA replaces Medicare's multiple quality reporting programs with a new single "MIPS" program, and also provides physicians with the option of being rewarded for participating in new alternative payment and delivery models to improve the quality and efficiency of care. To qualify for the APM bonus payments

under MACRA, physicians must bear “more than nominal financial risk,” report quality measures that are comparable to those in the MIPS program, and use certified EHR technology. To achieve the goals of delivery system reform, there is a need for changes to federal laws and regulations affecting hospital-physician arrangements, including the Physician Self-Referral Law (also known as “Stark”), the Anti-kickback law, and the Civil Monetary Penalties (CMP) Law. Since enactment of the self-referral law, 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.

The Department of Health and Human Service Office of Inspector General (OIG) and Centers for Medicare and Medicaid Services (CMS) have assisted with development of delivery and payment reform 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. These waivers only apply on a case-by-case basis to the specific models identified. Physician participation in new innovative payment and delivery models is critical for their success; however, physicians are reluctant to participate in these models because the self-referral and other federal laws prohibit the financial relationships necessary to achieve the clinical and financial integration necessary to be successful in reform. Specific concerns relate to prohibitions under the compensation standards of the Stark law and regulations, including “fair market value,” “volume or value,” and “other business generated” standards. These provisions make it difficult to structure incentive payments that reward physicians for improvements in quality and efficiency.

Congress took a step toward recognizing the need for change in the fraud and abuse laws when it recently limited the application of gain-sharing to the failure to provide medically necessary services. We recommend that a new “alternative payment model exception” be created to the Stark law or modify existing exceptions to enable financial arrangements that involve risk sharing and gain-sharing in alternative payment models when appropriate safeguards are in place. These arrangements pose little risk of program or patient abuse and are intended to provide better quality care.

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 criteria to meet this new exception. These conditions include the following:

- 1) Arrangements must be set forth in writing in advance, and be related to the contributions of the physicians to redesign and achieve quality and efficiency. The arrangement should specify the services to be provided and the incentive payment compensation methodology.
- 2) The total amount of Incentive Payment that a physician or physician group practice may receive from a Designated Health Services (DHS) entity is capped at 50 percent of the

Medicare physician fee schedule for services provided by that physician (or by the group) to beneficiaries for a given calendar year.

- 3) Receipt of the incentive payment is not conditioned on the volume or value of referrals or other business generated. Incentive payments must not be made knowingly to induce a physician to reduce or limit medically necessary items or services for their patients.
- 4) Beneficiary choice is maintained.
- 5) The agreement between the physician and the DHS entity must include criteria related to quality of care to be delivered by the physician to the beneficiaries during the episode.
- 6) The methodology for determining the incentive payments must be based, in part, on criteria related to, and inclusive of quality of care delivered.
- 7) The Quality criteria must be met to receive incentive payments.

It is imperative that these barriers be removed as quickly as possible. Therefore, the AAMC suggests that Congress urge CMS to exercise its existing authority to establish an “alternative payment model” exception under Stark. Alternatively, modifications can be made to existing exceptions to allow incentive payments to physicians participating in alternative payment models. For example, a revision could be made that would carve out compensation arrangements in alternative payment models that meet certain criteria from the “volume or value” standard under Stark which states that physician compensation cannot be determined in a manner that “takes into account the value or volume of referrals.” (See sections 1877(e)(1)(A)(iv), (e)(1)(B)(iv), (e)(2)(B)(ii), (e)(3)(A)(v), (e)(3)(B)(i), (e)(5)(B), (e)(6)(A), and (e)(7)(A)(v).) These criteria would in part be inclusive of quality of care delivered. In addition, CMS could modify the fair market value requirement in order to allow incentive payment arrangements. There should be a recognition that 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 APM. Concerns about fair market value could be addressed through setting safeguards related to quality, capping payments to physicians, and other criteria identified by CMS.

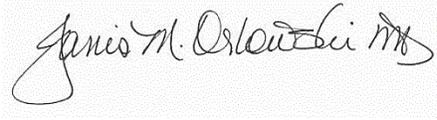
It is critical that CMS, the Office of Inspector General (OIG), and other associated agencies coordinate their efforts to allow waivers not only of the physician self-referral law, but also of the civil monetary penalties and anti-kickback laws, as appropriate to support the needed clinical and financial integration for the success of these new delivery and payment models. The highly regulated nature of the alternative payment models guard against the possibility that patients will be denied care or will be given poor quality care.

Given the increasing prevalence of payment programs that focus on meeting quality standards, 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 the criteria for the waivers and exceptions and making them broadly available rather than only being available on a program-by-program or case-by-case basis.

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If you would like to discuss these suggestions further, please contact Gayle Lee, [galee@aamc.org](mailto:galee@aamc.org), Ivy Baer, [ibaer@aamc.org](mailto:ibaer@aamc.org), or Len Marquez, [lmarquez@aamc.org](mailto:lmarquez@aamc.org).

Sincerely,

A handwritten signature in black ink that reads "Janis M. Orlowski M.D.". The signature is written in a cursive style with a large initial "J" and a stylized "M" at the end.

Janis M. Orlowski, M.D., M.A.C.P.  
Chief Health Care Officer

cc: Gayle Lee, JD, AAMC  
Ivy Baer, JD, AAMC  
Leonard Marquez, AAMC