



February 3, 2016

Kim Brandt
Chief Oversight Counsel
U.S. Senate
Committee on Finance
219 Dirksen Senate Office Building
Washington, DC 20510

Tegan Gelfand
Professional Staff Member
U.S. House of Representatives
Committee on Ways and Means
1102 Longworth House Office Building
Washington, DC 20515

Re: Invitation to Submit Comments on Stark Law Challenges and Potential Changes

Dear Ms. Brandt and Ms. Gelfand:

The American College of Physicians appreciates the efforts of the Senate Finance and House Ways and Means Committees to explore possible legislation to facilitate improvements in the Stark Law. The ACP is the largest medical specialty organization and the second-largest physician group in the United States. ACP members include 143,000 internal medicine physicians (internists), related subspecialists, and medical students. Internal medicine physicians are specialists who apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness.

The Stark Law, along with the Medicare Anti-Kickback, and Civil Monetary Penalty (CMP) Laws, all serve to decrease overutilization and inappropriate utilization, Medicare program costs, and the adverse influence of financial incentives on medical decision-making within the current volume-oriented fee-for-service healthcare payment system. The payment changes included in the recently passed Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) promote a different value-oriented approach, which de-emphasizes payment based on volume and emphasizes payment linked to improved care quality and the efficient use of healthcare resources (e.g., lower cost). This emphasis on value is present under both tracks available within MACRA: the Merit-Based Incentive Payment System (MIPS), which focuses on continued payment under the Physician Fee Schedule, but with a greater tie to value; and the Alternative Payment Model (APM) option, which encourages healthcare professionals to accept payment via advanced value-oriented models, such as the Patient-Centered Medical Home, the Medicare Shared Saving Program, and bundled payments. This new payment environment legitimately raises concern about regulatory controls under such statutes as Stark and anti-kickback. While necessary under traditional Medicare fee-for-service to address inappropriate increases in the volume of services that may be associated with self-referral arrangements, these statutes may impose unnecessary burdens and barriers under the value-based payment pathways, MIPS and APMs, created by MACRA. Or, of even greater concern, these regulatory controls may inhibit approaches and innovation related to such activities as care integration, care coordination, and patient engagement that are not only aligned with a value orientation, but also are beneficial both to the health of beneficiaries and the long-term solvency of the Medicare Trust Fund. Thus, this effort by Congress to re-evaluate and

improve the Stark Law through potential legislation is both timely and appropriate as we move toward value-based delivery and payment systems.

The Committees expressed particular interest in comments concerning the following issues:

I. Technical violations versus more serious or problematic violations --- and where to draw the line?

The Stark Law and related regulations do not formally distinguish between substantive and technical violations, and we commend the Committees for tackling this definitional problem. Our members are most concerned with technical violations --- those which make up the preponderance of Stark violations and generally stem from an inadequate understanding of this very complex set of regulations and/or from inadvertent omissions and inadequately updated paperwork. Resolution of these technical violations can also be very costly.

- The College believes that recent changes to the Stark law implemented within the 2016 Medicare Physician Fee Schedule Final Rule, including the easing of the signature, writing, and 1-year requirements, will assist covered entities in avoiding technical violations.
- The College encourages the Committee to consider the *Stark Administrative Simplification Act of 2015* (H.R. 776), which provides a uniform definition of “technical noncompliance” and offers a sanctions approach that is more reasonable and appropriate than the sanctions imposed under the current law.

The College is concerned that the Medicare self-referral disclosure protocol (SRDP), which sets forth a process to enable clinicians and suppliers to self-disclose actual or potential violations of the Stark statute and further provides a potential to reduce penalties resulting from these violations, is not fully serving its intended purpose. It appears to be underused, and we have heard complaints regarding the slowness of the determination process and the significant variability within the terms of the completed settlement. We request that the Committees look into this situation and determine ways in which this protocol option can be improved to better serve its purpose.

II. What changes need to be made to the Stark Law to implement MACRA in its current form and ACOs/shared savings programs?

As noted in our introductory paragraph, not only Stark, but also provisions of the Medicare anti-kickback and civil monetary penalties (CMP) laws have the potential to serve as unnecessary barriers towards physician and other healthcare professionals successfully performing within a value-oriented payment environment --- unnecessarily restricting referral relationships, compensation arrangements, gainsharing activities and other financial integration arrangements required to establish the necessary clinical and financial integration to achieve higher quality care at lower cost. The College offers the following for the Committees’ consideration:

- The College encourages legislatively mandating a report, similar to the “gainsharing report” under Section 512 of MACRA, requiring that the HHS Secretary review and assess not only the Stark Law, but also all the relevant Medicare program integrity statutes and related regulations (e.g., anti-kickback, CMP) within the context of the transformation of the healthcare environment created by MACRA. This effort should focus on: 1) potential barriers and unnecessary burdens that these laws and related regulations may place on the delivery of value-oriented care, and 2) suggested solutions to minimize or remove these barriers and burdens including the establishment of additional or expanded exceptions, safe harbors, and waivers.
- The Committees, in efforts to specifically improve the Stark Law, should place particular emphasis in the areas of compensation (e.g., clarifying and broadening methodology to define Fair Market Value) and expanding the waivers to Stark Law provisions that are currently highly restricted to specific programs (i.e., Medicare Shared Savings Program) to promote increased innovation and participation in new value-oriented alternative payment models. This expansion should include new programs being developed and tested through the Center for Medicare and Medicaid Innovation (CMMI) and qualifying APMs under MACRA.
- The College also requests that the Committees:
 - Take action to extend existing anti-kickback statute and Stark Law exceptions for donation and financial support of electronic health record (EHR) software, related technologies, and training beyond 2021. Many small physician practices are dependent on the donations and financial support of larger entities (e.g., hospitals, health systems) to develop the health information technological infrastructure to successfully provide services with a value-oriented payment environment.
 - Maintain the In-Office Ancillary Services (IOAS) exception under the Stark Law with appropriate safeguards (e.g., overutilization education, consequences for continued utilization outliers) to address concerns over physician ownership interests potentially contributing to unnecessary utilization. ACP policy affirms the continuation of the IOAS exception because it “enables physicians to provide convenient, onsite access to designated healthcare services (DHS) to their patients and better ensures patient adherence to recommended treatments. The exception also provides a structure that allows for increased quality oversight by the ordering physician, better care-coordination, and the potential for the provision of lower cost care compared to alternative settings (e.g.

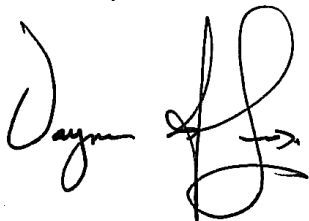
hospitals).”¹

- Investigate potential unintended liability under Stark and other federal program integrity statutes within the MIPS track under MACRA in the following situations:
 - A primary care physician practice enters into a formal or informal preferred referral agreement with specific neighboring independent medical specialty practices recognized for their promotion of care coordination and communication, delivery of high quality care and the efficient use of healthcare resources. The primary care practice is financially incentivized to refer to these specific specialty practices indirectly by allowing them to achieve higher scores under the quality and resource use performance categories in MIPS.
 - Medical practices form a “virtual group” and establish formally or informally a set of agreed-upon clinical protocols that will be used by all virtual group participants to try to achieve a high performance score within the quality performance category in MIPS.

In summary, the College appreciates the Committees’ recognition that the physician self-referral laws need to be revisited in light of the changes in health care delivery and payment reform. ACP is supportive of the increasing payment programs that focus on safe, efficient, value-based care delivery and agree that the Stark Self-Referral Laws should not prevent innovation. New organizational structures are often designed to streamline care and meet quality standards. This often means that providers of various sorts are bundled into service groups to best be able to improve patient safety and better quality of care. Some of the basic tenants of Stark Law do not easily allow for the participation of all providers in creating such successful outcomes, and share in the rewards of this good care.

ACP appreciates the opportunity to work with the Committees and provide our recommendations to improve Stark Law. If you have any questions, please do not hesitate to contact Neil Kirschner at 202-261-4535 or nkirschner@acponline.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Wayne J. Riley". The signature is stylized with a large, looped initial "W" and a long, sweeping horizontal stroke at the end.

Wayne J. Riley, MD, MPH, MBA, MACP
President, American College of Physicians

¹ American College of Physicians. “Update to ACP Policy Regarding the In-office Ancillary Services Exception.” Approved Nov. 2014. Accessed at: https://www.acponline.org/acp_policy/policies/policy_in-office_ancillary_services_exception_2014.pdf.