
# STATEMENT

**of the**

# American Medical Association

**to the**

**U.S. House of Representatives Committee on Ways and Means**
**Subcommittee on Health**

**Re: Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program**

**July 17, 2018**

**Division of Legislative Counsel**
**(202) 789-7426**

**STATEMENT**

**For the Record**

**of the**

**American Medical Association**

**to the**

**U.S. House of Representatives Committee on Ways and Means**
**Subcommittee on Health**

**Re: Modernizing Stark Law to Ensure the Successful Transition from Volume to Value in the Medicare Program**

**July 17, 2018**

The American Medical Association (AMA) appreciates the opportunity to provide our views regarding today's hearing on modernizing the Stark law to ensure the successful transition to value-based care. We commend the Health Subcommittee for holding this hearing and urge Congress and the Administration to update Stark to remove the barriers that impede value-based care.

According to the U.S. Department of Health and Human Services (HHS), the fraud and abuse laws "may serve as an impediment to robust, innovative programs that align providers by using financial incentives to achieve quality standards, generate cost savings, and reduce waste."[1] While everyone wants fraudsters to face appropriate punishment, there also is widespread acknowledgment that the fraud and abuse laws, like Stark, can stand in the way of payment and delivery system innovation.

Significant changes in health care payment and delivery have occurred since the enactment of Stark. Numerous initiatives are attempting to align payment and coordinate care to improve the quality and value of care delivered. Delivery of care is going through a digital transformation. However, Stark—in its almost thirty years of existence—has not commensurably changed.

Stark was enacted in a fee-for-service world that rewarded the volume of services. The fraud and abuse laws act as a deterrent against overutilization, inappropriate patient steering, and compromised medical judgment with heavy civil and criminal penalties like treble damages, exclusion from participation in federal health care programs, and potential jail time. As the Subcommittee notes, the health care system is moving to a world that rewards the outcome of the care provided. An important focus of payment reform is changing reimbursement models to emphasize the value or quality of care provided. However, this emphasis can run afoul of the

[1] Department of Health and Human Services, *Report to Congress Fraud and Abuse Laws Regarding Gainsharing or Similar Arrangements between Physicians and Hospitals As Required by Section 512(b) of the Medicare Access and CHIP Reauthorization Act of 2015* (2016), *available at* https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Report-to-Congress-2015.pdf.

fraud and abuse laws. For example, even if the primary purpose of an arrangement is to improve patients' outcomes, as long as one purpose of the arrangement's payments is to induce future referrals, the fraud and abuse laws are implicated (e.g., an arrangement that pays for a nurse coordinator to coordinate a recently discharged patient's care between a hospital, physician specialists, and a primary care physician may induce future referrals to the primary care physician to avoid an unnecessary readmission to the hospital).

Fostering the shift from volume to value has necessitated reviewing and, in some situations, updating fraud and abuse laws to ensure that they do not unduly impede the development of value-based payment. Through specific statutory authority, both the Centers for Medicare & Medicaid Services (CMS) and the Office of Inspector General (OIG) have deemed it necessary to waive the requirements of certain fraud and abuse laws to test the viability of innovative models that reward value and outcomes.

Outside of those models, however, the fraud and abuse laws may still pose barriers to initiatives that align payment with quality and improve care coordination. Tying compensation to the value of care provided, equipping providers with tools to improve care, and investing in tools to clinically and financially integrate all may run afoul of Stark. For example, it remains unclear how CMS will view measures that promote value given its long-standing belief that rewarding physicians for meeting utilization targets or for reducing or limiting services generally violates Stark.[2]

**Accordingly, the AMA urges Congress and the Administration to create a Stark exception to facilitate coordinated care and promote well-designed alternative payment models.** This exception should be broad, cover both the development and operation of a model to allow physicians to transition to an alternative payment model, and provide adequate protection for the entire care delivery process to include downstream care partners, entities, and manufacturers who are linking outcomes and value to the services or products provided.

Flexibility is important for innovation. Yet flexibility in a new payment system also may raise fraud and abuse concerns. To help address these concerns, the Stark exception could incorporate provisions that increased transparency and accountability through a board of directors approval; require the arrangement to be tied to the goals of the alternative payment model; and allow freedom of choice for patients by prohibiting stinting on medically necessary care.

While participation agreements work well in the context of specific payment models, the AMA believes they would likely be impractical for Medicare generally. As an alternative, the parties to the arrangement could set forth in writing the specifics of the arrangement, such as their goals for patient care quality, utilization, and costs, and the items and services covered under the arrangement.

While the focus of today's hearing is on Stark, Stark interacts with other fraud and abuse laws that also need to be modernized, i.e., the anti-kickback statute and the civil monetary penalties law. The AMA asks that Congress and the Administration set forth clear and commonsense

[2] 69 Fed. Reg. 16054, 16088 (Mar. 24. 2004); 72 Fed. Reg. 51052; 51046 (Sept. 5, 2007).

exceptions and safe harbors concerning the formation of innovative delivery models so that physicians can pursue integration options that are not hospital driven.[3]

Physician leadership in these new efforts is instrumental to optimizing care, improving population health, and reducing costs. Physicians provide the care, take care of the patients, and see the cost inefficiencies and overutilization. Physicians should not have to be employed by a hospital or sell their practice to a hospital in order to participate in innovative delivery models. Ultimately, physicians should be able to maintain their independent practice while at the same time have access to the infrastructure and resources necessary to participate in alternative payment models.

The AMA applauds the Subcommittee's efforts to improve the Stark Law and appreciates the opportunity to provide our comments on this important topic. We look forward to working with Congress on ensuring that legal structures keep pace with evolving health care delivery and payment systems.

[3] Although OIG has the regulatory authority to create an anti-kickback safe harbor, CMS, by statute, must show no program or patient abuse in creating Stark exceptions. 42 U.S.C. § 1395nn(b)(4). This Stark standard is difficult for CMS to meet and has caused other proposed regulatory Stark exceptions to fail.