



August 22, 2018

Seema Verma, Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1720-NC  
P.O. Box 8013  
Baltimore, MD 21244-8013

Dear Administrator Verma:

On behalf of the American Academy of Family Physicians (AAFP), which represents 131,400 family physicians and medical students across the country, I write in response to the [request for information](#) regarding the physician self-referral law as published by the Centers for Medicare & Medicaid Services (CMS) in the June 25, 2018, *Federal Register*.

Initially enacted in 1989, the physician self-referral law, also known as the “Stark Law,” addressed the concern that clinical decision-making can be unduly influenced by self-referral. Financial incentives in patient referrals may improperly influence utilization, patient choice, and competition. The physician self-referral law is intended to disconnect a physician’s clinical decision-making from his or her financial interests. CMS recognizes the effect the physician self-referral law may have on parties participating or contemplating participation in integrated delivery models, alternative payment models, and arrangements to incentivize improvements in outcomes and reduction in cost.

The AAFP appreciates the opportunity to comment on CMS’s “Request for Information Regarding the Physician Self-Referral Law.” **The AAFP urges CMS to ensure that the Stark Law does not hinder family physicians’ ability to transform their practices and collaborate with other physicians and health care professionals to provide team-based, patient-centered care that incorporates new technologies and focuses on reducing the total cost of care. Overall, CMS must make available clear safe harbors for advanced primary-care models, covering operational and financial arrangements as well as physician practice and flexibility.**

#### Need for Clarity

America’s family physicians generate a significant volume of referrals for services within the Medicare program. As such, family medicine practices frequently seek professional advice when they add lines of service to their own practices (e.g. laboratory services, physical or nutritional therapy, as well as imaging), if they plan to refer their own Medicare patients to such services. Family physicians often can refer their patients within the practice in compliance with the Stark Law, under the in-office ancillary services (IOAS) exception.

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However, the complexity of the Stark laws and their implementing regulations cause family-medicine practices to seek expensive legal advice on their billing arrangements out of concern regarding self-referral laws. **The AAFP urges CMS to create broad and clear safeguards for value-based payment arrangements. Until CMS provides clarity, practicing family physicians will continue to struggle to understand physician-self referral laws. The AAFP strongly urges CMS to create a simple decision tree for medical practices to help determine if further costly legal opinions may be needed.**

#### Alternative Payment Models (APMs)

As the move to value-based care continues, the AAFP expects existing and future APMs under MACRA to accelerate the need to coordinate and integrate care across payment and delivery settings—and will likely give rise to substantial need for waivers for physicians from the Stark Law. **We encourage CMS to work with Congress to obtain the appropriate waiver authority to promote APMs and drive value-based care.**

In addition, CMS now has the opportunity to test new models that have been vetted and submitted by the Physician Focused Payment Model Technical Advisory Committee (PTAC). In a [letter](#) dated February 28, 2018, the PTAC submitted to Secretary Azar a unanimous recommendation to test the advanced primary-care APM (APC-APM). As you move to testing and scale up this and other physician-focused models, the AAFP encourages CMS to remove any potential Stark barriers that would inhibit successful uptake and proliferation of these models.

#### Merit-Based Incentive Payment System

The AAFP does not view the MIPS framework as substantially different from legacy fee-for-service payment such that it will impact the application of the Stark Law on family-physician referral patterns. However, the AAFP advises CMS to closely monitor two issues. First, the complexity of MIPS may accelerate the current consolidation of health systems with independent physician practices—if independent practices struggle to meet the additional administrative burden imposed on them by MIPS. Second, MIPS gives practices the authority to combine into “voluntary virtual groups” for MIPS reporting and payment purposes. **To the extent that physician practices within such virtual groups might need safe harbor from the Stark Law (for example, if they begin to exhibit certain characteristics of a group practice yet are not eligible for the “group practice” exception to the Stark Law), CMS should closely monitor as MIPS virtual groups develop.**

#### Role of transparency

The AAFP policy titled “[Transparency](#)” states that the AAFP “believes that transparency in health care refers to reporting information which can be easily verified for accuracy. Both data and process should have transparency and an explicit disclosure of data limitations.” The [AAFP recognizes](#) the potential value of Medicare physician claims data. If used correctly, it can potentially provide accurate and meaningful information to patients, physicians, and other stakeholders that could improve quality at the point of care.

CMS asks, “if provided by the referring physician to a beneficiary, would transparency about physician’s financial relationships, price transparency, or the availability of other data necessary for informed consumer purchasing (such as data about quality of services provided) reduce or eliminate the harms to the Medicare program and its beneficiaries that the physician self-referral

law is intended to address?” **AAFP policies affirm that transparency in all forms would reduce harms to Medicare patients.**

#### Need to address three-day inpatient hospital stay

Other archaic barriers in federal laws and regulations that may prevent or discourage needed changes in delivery beyond the provisions of the Stark Law include, but are not limited to, the requirement that patients must have a three-day inpatient hospital stay as a prerequisite for coverage of skilled nursing facility care. CMS should waive the three-day rule where it has authority to do so and work with Congress to eliminate the provision from the Medicare statute.

#### Definitions

- *Care coordination*- The AAFP urges CMS to define “Care coordination” so that primary care is explicitly recognized as the first point of contact for many patients, and therefore is the center of patient experience with health care. It should be noted that primary care is best positioned to coordinate care across settings and among physicians in most cases. Primary care medical homes work closely with patients' other health care providers to coordinate and manage care transitions, referrals, and information exchange. An advanced primary care practice is one that is based on the [Joint Principals of the Patient Centered Medical Home](#) and has adopted the five key functions of CPC+.
- *Risk* - The term “risk” by itself is ambiguous. CMS should be explicit in setting forth whether the term describes financial, health, performance, or insurance risk. We urge CMS to define the type of risk in the discussion for clarity.

We appreciate the opportunity to provide this feedback. Please contact Robert Bennett, Federal Regulatory Manager, at 202-232-9033 or [rbennett@aafp.org](mailto:rbennett@aafp.org) with any questions or concerns.

Sincerely,

A handwritten signature in black ink, appearing to read 'John Meigs, Jr.', with a stylized flourish and the initials 'MS' at the end.

John Meigs, Jr., MD, FAFBP  
Board Chair

#### **About Family Medicine**

Family physicians conduct approximately one in five of the total medical office visits in the United States per year – more than any other specialty. Family physicians provide comprehensive, evidence-based, and cost-effective care dedicated to improving the health of patients, families and communities. Family medicine’s cornerstone is an ongoing and personal patient-physician relationship where the family physician serves as the hub of each patient’s integrated care team. More Americans depend on family physicians than on any other medical specialty.